likely demand for such risk evaluations, and the anticipated schedule for accommodating that demand;

"(C) the capacity of the Environmental Protection Agency to promulgate rules under section 6(a) as required based on risk evaluations conducted and published under section 6(b); and

"(D) the actual and anticipated efforts of the Environmental Protection Agency to increase the Agency's capacity to conduct and publish risk evaluations under section 6(b).

"(2) SUBSEQUENT REPORTS.—The Administrator shall update and resubmit the report described in paragraph (1) not less frequently than once every 5 years.".

SEC. 9. CONFORMING AMENDMENTS.

(a) SECTION 4.—Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amended—

(1) in subsection (b)—

(A) in paragraph (1), by striking "rule" each place it appears and inserting "rule, order, or consent agreement";

(B) in paragraph (2)(B), by striking "rules" and inserting "rules, orders, and consent agreements";

(C) in paragraph (3), by striking "rule" each place it appears and inserting "rule, order, or consent agreement"; and

(D) in paragraph (4)—

(i) by striking "rule under subsection (a)" each place it appears and inserting "rule, order, or consent agreement under subsection (a)";

(ii) by striking "repeals the rule" each place it appears and inserting "repeals the rule or order or modifies the consent agreement to terminate the requirement"; and

(iii) by striking "repeals the application of the rule" and inserting "repeals or modifies the application of the rule, order, or consent agreement";

(2) in subsection (c)—

(A) in paragraph (1), by striking "rule" and inserting "rule or order";

(B) in paragraph (2)—

(i) in subparagraph (A), by striking "a rule under subsection (a) or for which data is being developed pursuant to such a rule" and inserting "a rule, order, or consent agreement under subsection (a) or for which data are being developed pursuant to such a rule, order, or consent agreement";

(ii) in subparagraph (B), by striking "such rule or which is being developed pursuant to such rule" and inserting "such rule, order, or consent agreement or which is being developed pursuant to such rule, order, or consent agreement"; and

(iii) in the matter following subparagraph (B), by striking "the rule" and inserting "the rule or order";

(C) in paragraph (3)(B)(i), by striking "rule promulgated" and inserting "rule, order, or consent agreement"; and

(D) in paragraph (4)—

(i) by striking "rule promulgated" each place it appears and inserting "rule, order, or consent agreement";

(ii) by striking "such rule" each place it appears and inserting "such rule, order, or consent agreement"; and

(iii) in subparagraph (B), by striking "the rule" and inserting "the rule, order, or consent agreement";

(3) in subsection (d), by striking "rule" and inserting "rule, order, or consent agreement"; and

(4) in subsection (g), by striking "rule" and inserting "rule, order, or consent agreement".

(b) SECTION 5.—Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

(1) in subsection (b)—

(A) in paragraph (1)(A)—

(i) by striking "rule promulgated" and inserting "rule, order, or consent agreement"; and

(ii) by striking "such rule" and inserting "such rule, order, or consent agreement";

(B) in paragraph (1)(B)—

(i) by striking "rule promulgated" and inserting "rule or order"; and

(ii) by striking "the date of the submission in accordance with such rule" and

inserting "the required date of submission"; and

(C) in paragraph (2)(A)(ii), by striking "rule promulgated" and inserting "rule, order, or consent agreement";

(2) in subsection (d)(2)(C), by striking "rule" and inserting "rule, order, or consent agreement"; and

(3) in subsection (h)(4), by striking "paragraphs (2) and (3) of section 6(c)" and inserting "paragraph (2) of section 6(c)".

(c) SECTION 6.—Section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) is amended—

(1) in subsection (d)(2)(B)—

(A) by striking ", provide reasonable opportunity, in accordance with paragraphs (2) and (3) of subsection (c), for a hearing on such rule," and inserting "in accordance with paragraph (2) of subsection (c),"; and

(B) by striking "; and if such a hearing is requested" and all that follows through "or revoke it." and inserting a period; and

(2) in subsection (e)(4), by striking "paragraphs (2), (3), and (4) of subsection (c)" and inserting "paragraph (2) of subsection (c)".

(d) SECTION 7.—Section 7(a)(1) of the Toxic Substances Control Act (15 U.S.C. 2606(a)(1)) is amended, in the matter following subparagraph (C), by striking "a rule under section 4, 5, 6, or title IV or an order under section 5 or title IV" and inserting "a rule under section 4, 5, or 6 or title IV, an order under section 4 or 5 or title IV, or a consent agreement under section 4".

(e) SECTION 8.—Section 8(a)(3)(A)(ii)(I) of the Toxic Substances Control Act (15 U.S.C. 2607(a)(3)(A)(ii)(I)) is amended by striking "or an order in effect under section 5(e)" and inserting ", an order in effect under section 4 or 5(e), or a consent agreement under section 4".

(f) SECTION 9.—Section 9(a) of the Toxic Substances Control Act (15 U.S.C. 2608(a)) is amended by striking "section 6" each place it appears and inserting "section 6(a)".

(g) SECTION 11.—Section 11(b)(2)(E) of the Toxic Substances Control Act (15 U.S.C. 2610(b)(2)(E)) is amended by striking "rule promulgated" and inserting "rule promulgated, order issued, or consent agreement entered into".

(h) SECTION 15.—Section 15(1) of the Toxic Substances Control Act (15 U.S.C. 2614(1)) is amended by striking "(A) any rule" and all that follows through "or

(D)'' and inserting ''any requirement of this title or any rule promulgated, order issued, or consent agreement entered into under this title, or''.

(i) SECTION 18.—Section 18(a)(2)(A) of the Toxic Substances Control Act (15 U.S.C. 2617(a)(2)(A)) is amended—

(1) by striking ''rule promulgated'' and inserting ''rule, order, or consent agreement''; and

(2) by striking ''such rule'' each place it appears and inserting ''such rule, order, or consent agreement''.

(j) SECTION 19.—Section 19 of the Toxic Substances Control Act (15 U.S.C. 2618) is amended—

(1) in subsection (a)—

(A) in paragraph (1)(A)—

(i) by striking ''(A) Not later than 60 days after the date of the promulgation of a rule'' and inserting ''Not later than 60 days after the date on which a rule is promulgated'';

(ii) by inserting ''or the date on which an order is issued under section 4,'' before ''any person'';

(iii) by striking ''such rule'' and inserting ''such rule or order''; and

(iv) by striking "such a rule" and inserting "such a rule or order";

(B) by striking paragraph (1)(B);

(C) in paragraph (2), by striking "the rule" and inserting "the rule or order"; and

(D) in paragraph (3)—

(i) in subparagraph (A), by striking "the rule" and inserting "the rule or order";

(ii) in subparagraph (B), by striking "a rule under section 4(a)" and inserting "a rule or order under section 4(a)";

(iii) in subparagraph (C), by striking "such rule" and inserting "such rule or order";

(iv) in subparagraph (D), by striking "such rule" and inserting "such rule or order"; and

(v) in subparagraph (E)—

(I) by striking "to such rule" and inserting "to such rule or order"; and

(II) by striking "the date of the promulgation of such rule" and inserting "the date on which such rule

is promulgated or such order is issued";

(2) in subsection (b)—

(A) by striking "review a rule" and inserting "review a rule, or an order under section 4,";

(B) by striking "such rule" and inserting "such rule or order";

(C) by striking "the rule" and inserting "the rule or order";

(D) by striking "new rule" each place it appears and inserting "new rule or order"; and

(E) by striking "modified rule" and inserting "modified rule or order"; and

(3) in subsection (c)—

(A) in paragraph (1)—

(i) in subparagraph (A)—

(I) by striking "a rule" and inserting "a rule, or an order under section 4"; and

(II) by striking "such rule" and inserting "such rule or order"; and

(ii) in subparagraph (B)—

(I) in the matter preceding clause (i), by striking "a rule" and inserting "a rule or order";

(II) in clause (i)—

(aa) by inserting "or an order under section 4," before "the standard for review";

(bb) by striking "such rule" and inserting "such rule or order";

(cc) by striking "the rule" and inserting "the rule or order"; and

(dd) by striking the semicolon and inserting "; and"; and

(III) by striking clause (ii) and redesignating clause (iii) as clause (ii); and

(B) in paragraph (2), by striking "any rule" and inserting "any rule or order".

(k) SECTION 20.—Section 20(a)(1) of the Toxic Substances Control Act (15 U.S.C. 2619(a)(1)) is amended by striking "order issued under section 5" and inserting "order issued under section 4 or 5".

(l) SECTION 21.—Section 21 of the Toxic Substances Control Act (15 U.S.C. 2620) is amended—

(1) in subsection (a), by striking "order under section 5(e) or (6)(b)(2)" and inserting "order under section 4 or 5(e)"; and

(2) in subsection (b)—

(A) in paragraph (1), by striking "order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)" and inserting "order under section 4 or 5(e)"; and

(B) in paragraph (4)(B)—

(i) in the matter preceding clause (i), by striking "order under section 5(e) or 6(b)(2)" and inserting "order under section 4 or 5(e)";

(ii) in clause (i), by striking "order under section 5(e)" and inserting "order under section 4 or 5(e)"; and

(iii) in clause (ii), by striking "or an order under section 6(b)(2)".

(m) SECTION 24.—Section 24(b)(2)(B) of the Toxic Substances Control Act (15 U.S.C. 2623(b)(2)(B)) is amended—

(1) by inserting "and" at the end of clause (i);

(2) by striking clause (ii); and

(3) by redesignating clause (iii) as clause (ii).

(n) SECTION 27.—Section 27(a) of the Toxic Substances Control Act (15 U.S.C. 2626(a)) is amended by striking "rules promulgated" and inserting "rules, orders, or consent agreements".

(o) SECTION 30.—Section 30(2) of the Toxic Substances Control Act (15 U.S.C. 2629(2)) is amended by striking "rule" and inserting "rule, order, or consent agreement".

Passed the House of Representatives June 23, 2015.

Attest: KAREN L. HAAS,

Clerk.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 11/30/2015 9:55:49 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA Requests
Attachments: Sen. Markey TSCA TA on animal testing.docx; Sen. Markey TSCA TA on CBI.docx

Michal – Attached are two documents on animal testing and CBI that are excerpted from the comprehensive Senate TA previously sent. We are reconciling House CBI and expect to have that ready tomorrow. Please let me know if this is what you are looking for and if a followup call needed. Thanks,
Sven

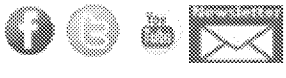
Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, November 30, 2015 10:34 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Requests

Nothing specific – on animal testing and CBI, past TA is totally fine, but what I have seen on CBI in the past TA has been on a Senate version that is very different from the current version. I also haven't seen anything by way of TA on the House CBI provision. I don't want you to spend a ton of time developing new material.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, November 30, 2015 10:09 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Requests

Michal – we're getting together this morning to review the TSCA TA requests. On the new animal testing and CBI questions – is there anything specific? If not, we can review past TA, some that you already have in the comprehensive Senate bill TA, and put something together. Please let me know if any requests are more urgent than others to help with prioritizing. Thanks,
Sven

Sven-Erik Kaiser

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This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

TSCA TA on animal testing in the manager's amendment version of S.697

SEC. 5. TESTING OF CHEMICAL SUBSTANCES OR MIXTURES.

(a) In General.—Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amended—

* * *

~~(5)~~**(3)** by inserting before subsection (f) ~~(as so redesignated)~~ the following:

* * *

"(c) Reduction of Testing on Vertebrates.—

"(1) IN GENERAL.—The Administrator shall minimize, to the extent practicable, the use of vertebrate animals in testing of chemical substances or mixtures, by—

"(A) ~~encouraging and facilitating—~~ **prior to making a request or adopting a requirement for testing using vertebrate animals, taking into consideration, as appropriate and to the extent practicable, reasonably available—**

"(i) toxicity information;

"(ii) computational toxicology and bioinformatics;

**** 1** "(iii) high-throughput screening methods and the prediction models of those methods; and

**** 2** "(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information~~.~~**;**

"(B) encouraging and facilitating—

"(i) the use of integrated and tiered testing and assessment strategies;

"(ii) the use of best available science in existence on the date on which the test is conducted;

"(iii) the use of test methods that eliminate or reduce the use of animals while providing information of high scientific quality;

"(iv) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide reliable and useful information on other chemical substances in the category;

"(v) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests; and

"(vi) the submission of information from—

"(I) animal-based studies; and

"(II) emerging methods and models; and

"~~(B)~~**"(C)** funding research and validation studies to reduce, refine, and replace the use of animal tests in accordance with this subsection.

"(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new testing methods that are not based on vertebrate animals, the Administrator shall—

"(A) not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information under this title that can reduce, refine, or replace the use of vertebrate animals, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening;

"(B) as practicable, ensure that the strategic plan developed under subparagraph (A) is reflected in the development of requirements for testing under this section;

"(C) identify in the strategic plan developed under subparagraph (A) particular alternative test methods or testing strategies that do not require new vertebrate animal testing and are scientifically reliable, relevant, and capable of providing information of equivalent scientific reliability and quality to that which would be obtained from vertebrate animal testing;

"(D) provide an opportunity for public notice and comment on the contents of the plan developed under subparagraph (A), including the criteria for considering scientific reliability, relevance, and equivalent information and the test methods and strategies identified in subparagraph (C);

"(E) beginning on the date that is 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing this subsection and goals for future alternative test methods implementation;

"(F) fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and testing strategies that reduce, refine, or replace the use of vertebrate animals in any testing under this title; and

"(G) identify synergies with the related information requirements of other jurisdictions to minimize the potential for additional or duplicative testing.

"(3) CRITERIA FOR ADAPTING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct testing of a chemical substance or mixture on vertebrate animals under this section, the Administrator may adapt or waive the requirement, if the Administrator determines that—

"(A) there is sufficient evidence from several independent sources of information to support a conclusion that a chemical substance or mixture has, or does not have, a particular property if the information from each individual source alone is insufficient to support the conclusion;

"(B) as a result of 1 or more physical or chemical properties of the chemical substance or mixture or other toxicokinetic considerations—

"(i) the substance cannot be absorbed; or

"(ii) testing for a specific endpoint is technically not practicable to conduct; or

"(C) a chemical substance or mixture cannot be tested in vertebrate animals at concentrations that do not result in significant pain or distress, because of physical or chemical properties of the chemical substance or mixture, such as a potential to cause severe corrosion or severe irritation to the tissues of the animal.

"(4) VOLUNTARY TESTING.—

"(A) IN GENERAL.—Any person developing information for submission under this title on a voluntary basis and not pursuant to any request or requirement by the Administrator shall first attempt to develop the information by means of an alternative or nonanimal test method or testing strategy that the Administrator has determined under paragraph (2)(C) to be scientifically reliable, relevant, and capable of providing equivalent information, before conducting new animal testing.

"(B) EFFECT OF PARAGRAPH.—Nothing in this paragraph—

"(i) requires the Administrator to review the basis on which the person is conducting testing described in subparagraph (A);

"(ii) prohibits the use of other test methods or testing strategies by any person for purposes other than developing information for submission under this title on a voluntary basis; or

"(iii) prohibits the use of other test methods or testing strategies by any person, subsequent to the attempt to develop information using the test methods and testing strategies identified by the Administrator under paragraph (2)(C).

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

SEC. 14. CONFIDENTIAL INFORMATION.

Section 14 of the Toxic Substances Control Act (15 U.S.C. 2613) is amended to read as follows:

"SEC. 14. CONFIDENTIAL INFORMATION.

"(a) In General.—Except as otherwise provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, under subsection (b)(4) of that section—

"(1) that is reported to, or otherwise obtained by, the Administrator under this Act; and

"(2) for which the requirements of subsection (d) are met.

"(b) Information Generally Protected From Disclosure.—The following information specific to, and submitted by, a manufacturer, processor, or distributor that meets the requirements of subsections (a) and (d) shall be presumed to be protected from disclosure, subject to the condition that nothing in this Act prohibits the disclosure of any such information, or information that is the subject of subsection (g)(3), through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law:

"(1) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

"(2) Marketing and sales information.

"(3) Information identifying a supplier or customer.

"(4) Details of the full composition of a mixture and the respective percentages of constituents.

"(5) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or product.

"(6) Specific production or import volumes of the manufacturer ~~and specific~~.

"(7) Specific aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

~~"(7)~~**"(8)** Except as otherwise provided in this section, the specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, **if** ~~if—~~

~~"(A)~~ the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5~~; and~~

~~"(B) the claim—~~

~~"(i) is not subject to an exception under subsection (e); or~~

~~"(ii) has not subsequently been withdrawn or found by the Administrator not to warrant~~

Commented [A1]: As we have previously pointed out, it makes no sense to condition presumptive protection on whether the information actually meets the CBI standard in (a). In addition, this may increase the number of CBI claims EPA must review, since EPA may not be able treat information as falling under (b) and hence not subject to review without first determining it is CBI.

Commented [A2]: As we have previously pointed out, this proviso for *presumptive* CBI suggests that other CBI will be shielded from discovery, etc.

Commented [A3]: The point of this provision presumably is to protect chem id in advance of an NOC, but some pre-NOC distribution would likely be considered offered for commercial distribution under TSCA (e.g., distribution for R&D).

Conversely, some post-NOC manufacturing, processing, and distribution might not qualify as "offer[ing]" the chemical to another party, and so arguably might not fall under this heading.

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~~protection as confidential information under subsection (f)(2) or (g)~~.

"(c) Information Not Protected From ~~Disclosure.—Notwithstanding~~ **Disclosure.—**

"(1) IN GENERAL.—Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:

~~"(1)~~**"(A)** INFORMATION FROM HEALTH AND SAFETY STUDIES.—

~~"(A)~~**"(i)** IN GENERAL.—Subject to ~~subparagraph (B), subsection (a) does not prohibit the disclosure of—~~ **clause (ii)—**

~~"(i)~~**"(I)** any health and safety study that is submitted under this Act with respect to—

~~"(I)~~**"(aa)** any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

~~"(II)~~**"(bb)** any chemical substance or mixture for which—

~~"(aa)~~**"(AA)** testing is required under section 4; or

~~"(bb)~~**"(BB)** a notification is required under section 5; or

~~"(ii)~~**"(II)** any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in ~~subclause (I) or (II) of clause (i).~~ **item (aa) or (bb) of subclause (I).**

~~"(B)~~**"(ii)** EFFECT OF ~~PARAGRAPH.—NOTHING~~ **SUBPARAGRAPH.—Nothing** in this ~~paragraph~~ **subparagraph** authorizes the release of any information that discloses—

~~"(i)~~**"(I)** a process used in the manufacturing or processing of a chemical substance or mixture; or

~~"(ii)~~**"(II)** in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

~~* 4 "(2) Certain requests.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is described in paragraph (1) that is not described in paragraph (1)(B), the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.~~

~~"(3)~~**"(B)** OTHER INFORMATION NOT PROTECTED FROM ~~DISCLOSURE.—THE FOLLOWING INFORMATION IS NOT PROTECTED FROM DISCLOSURE UNDER THIS SECTION:~~ **DISCLOSURE.—**

~~"(A)~~**"(i)** For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered

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for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

"~~(B)~~**"(ii)** A safety assessment developed, or a safety determination made, under section 6.

"~~(C)~~**"(iii)** Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

"~~(D)~~**"(iv)** A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

Commented [A4]: As we have previously pointed out, this adds nothing and could create confusion, since the point it makes for specific chem id is true for all information – ie, it cannot be CBI if not properly claimed.

"~~(4)~~**"(2)** MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION .—Any information that is ~~otherwise~~ eligible for protection under this section and ~~contained in a submission of~~ **is submitted with** information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

"~~(5)~~**"(3)** BAN OR PHASE-OUT.—If the Administrator promulgates a rule pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance, subject to paragraphs (2), (3), and (4) of subsection (g), any protection from disclosure provided under this section with respect to the specific identity of the chemical substance and other information relating to the chemical substance shall no longer apply.

** **4** "~~(2)~~**"(4)** CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is ~~described in paragraph (1) that is not described in paragraph (1)(B)~~ **subject to disclosure under this subsection**, the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

"(d) Requirements for Confidentiality Claims.—

"(1) ASSERTION OF CLAIMS.—

"(A) IN GENERAL.—A person seeking to protect any information submitted under this Act from disclosure (including information described in subsection (b)) shall assert to the Administrator a claim for protection concurrent with submission of the information, in accordance with such rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this title.

"(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a

statement that the person has—

"(i) taken reasonable measures to protect the confidentiality of the information;

"(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

"(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

"(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

"(C) SPECIFIC CHEMICAL IDENTITY.—In the case of a claim under subparagraph (A) for protection against disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that the generic name shall—

"(i) ~~conform~~ **be consistent** with guidance ~~prescribed~~ **issued** by the Administrator under paragraph (3)(A); and

"(ii) describe the chemical structure of the substance as specifically as practicable while protecting those features of the chemical structure—

"(I) that are considered to be confidential; and

"(II) the disclosure of which would be likely to **cause substantial** harm **to** the competitive position of the person.

"(D) PUBLIC INFORMATION.—No person may assert a claim under this section for protection from disclosure of information that is already publicly available.

"(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—Except for information described in ~~paragraphs (1) through (7) of~~ subsection (b), a person asserting a claim to protect information from disclosure under this Act shall substantiate the claim, in accordance with the rules promulgated and **consistent with the** guidance issued by the Administrator.

"(3) GUIDANCE.—The Administrator shall develop guidance regarding—

"(A) the determination of structurally descriptive generic names, in the case of claims for the protection against disclosure of specific chemical identity; and

"(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (e).

"(4) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the ~~information that has been submitted is~~ **statement required to assert a claim submitted pursuant to paragraph (1)(B) and any information required to substantiate a claim submitted pursuant to paragraph (2) are** true and correct.

"(e) Exceptions to Protection From Disclosure.—Information described in subsection (a)—

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"(1) shall be disclosed if the information is to be disclosed to an officer or employee of the United States in connection with the official duties of the officer or employee—

"(A) under any law for the protection of health or the environment; or

"(B) for a specific law enforcement purpose;

"(2) shall be disclosed if the information is to be disclosed to a contractor of the United States and employees of that contractor—

"(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act; and

"(B) subject to such conditions as the Administrator may specify;

"(3) shall be disclosed if the Administrator determines that disclosure is necessary to protect health or the environment;

"(4) shall be disclosed if the information is to be disclosed to a State or political subdivision of a State, on written request, for the purpose of development, administration, or enforcement of a law, **if** ~~if—~~

~~"(A)~~ 1 or more applicable agreements with the Administrator that ~~conform~~ **are consistent** with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information; ~~and~~

~~"(B) the Administrator notifies the person that submitted the information that the information has been disclosed to the State or political subdivision of a State;~~

"(5) shall be disclosed if a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

"(A) the statement of need and confidentiality agreement ~~shall conform~~ **are consistent** with the guidance issued under subsection (d)(3)(B);

"(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

"(i) the information is necessary for, or will assist in—

"(I) the diagnosis or treatment of 1 or more individuals; or

"(II) responding to an environmental release or exposure; and

"(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

"(C) the confidentiality agreement shall provide that the person will not use the

information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

"(6) shall be disclosed if in the event of an emergency, a treating physician, nurse, agent of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder (including any individual duly authorized by a Federal agency, State, or political subdivision of a State who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) requests the information, subject to the conditions that—

"(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable basis to suspect that—

"(i) a medical or public health or environmental emergency exists;

"(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

"(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred;

"(B) if requested by the person submitting the information to the Administrator, the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

"(i) provide a written statement of need; and

"(ii) agree to sign a confidentiality agreement; and

"(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed;

"(7) may be disclosed if the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure shall be made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding;

"(8) shall be disclosed if the information is to be disclosed, on written request of any duly authorized congressional committee, to that committee; or

"(9) shall be disclosed if the information is required to be disclosed or otherwise made public under any other provision of Federal law.

"(f) Duration of Protection From Disclosure.—

"(1) IN GENERAL.—

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"(A) INFORMATION ~~PROTECTED~~ **NOT SUBJECT TO TIME LIMIT FOR PROTECTION** FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information **described in subsection (b)** that meets the requirements of ~~subsection (d) for a period of 10 years, unless, prior to the expiration of the period—~~ **subsections (a) and (d), unless—**

~~"(i) an affected person~~ **"(i) the person that asserted the claim** notifies the Administrator that the person is withdrawing the ~~confidentiality~~ claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the ~~need for protection from disclosure can no longer be substantiated~~ **information does not qualify or no longer qualifies for protection against disclosure under subsection (a)**, in which case the Administrator shall take ~~the~~ **any** actions ~~described in~~ **required under** subsection (g)(2).

"(B) **INFORMATION SUBJECT TO TIME LIMIT FOR PROTECTION FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information, other than information described in subsection (b), that meets the requirements of subsections (a) and (d) for a period of 10 years, unless, prior to the expiration of the period—**

"(i) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the information does not qualify or no longer qualifies for protection against disclosure under subsection (a), in which case the Administrator shall take any actions required under subsection (g)(2).

"(C) EXTENSIONS.—

"(i) IN GENERAL.—Not later than the date that is 60 days before the expiration of the period described in subparagraph ~~(A)~~**(B)**, the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

"(ii) STATEMENT.—

"(I) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in subparagraph ~~(A)~~**(B)**, a person reasserting the relevant claim shall submit to the Administrator a ~~statement~~ **request for extension** substantiating, in accordance with subsection (d)(2), the need to extend the period.

"(II) ACTION BY ADMINISTRATOR.—Not later than the date ~~that is 30 days after the date of receipt of a statement under subclause (I), the Administrator shall—~~ **of expiration of the period described in subparagraph (B), the**

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Administrator shall, in accordance with subsection (g)(1)(C)—

"(aa) review the request **submitted under subclause (I)**;

"(bb) make a determination regarding whether the ~~information~~ **claim** for which the request ~~is made~~ **was submitted** continues to meet the relevant criteria established under this section; and

"(cc)(AA) grant an extension of ~~not more than~~ 10 years; or

"(BB) deny the ~~claim.~~ **request.**

~~"(C)~~**"(D)** NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under subparagraph ~~(B)~~**(C)**, if the Administrator determines that the relevant ~~statement~~ **request** under subparagraph ~~(B)(ii)(I)~~ **(C)(ii)(I)**—

"(i) establishes the need to extend the period; and

"(ii) meets the requirements established by the Administrator.

"(2) REVIEW AND RESUBSTANTIATION.—

"(A) DISCRETION OF ADMINISTRATOR.—The Administrator may review, at any time, a claim for protection **of information** against disclosure under subsection (a) ~~for information submitted to the Administrator regarding a chemical substance~~ and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) after the chemical substance is identified as a high-priority substance under section 4A;

"(ii) for any chemical substance for which the Administrator has made a determination under section 6(c)(1)(C);

"(iii) for any inactive chemical substance identified under section 8(b)(5); or

"(iv) in limited circumstances, if the Administrator determines that disclosure of certain information currently protected from disclosure would assist the Administrator in conducting safety assessments and safety determinations under subsections (b) and (c) of section 6 or promulgating rules pursuant to section 6(d), ~~subject to the condition that the information shall not be disclosed unless the claimant withdraws the claim or the Administrator determines that the information does not meet the requirements of subsection (d)~~.

Commented [A5]: Reference should be to 8(b)(5)(B) specifically – change to active status.

"(B) REVIEW REQUIRED.—The Administrator shall review a claim for protection ~~from~~ **of information against** disclosure under subsection (a) ~~for information submitted to the Administrator regarding a chemical substance~~ and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to

withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) as necessary to ~~comply~~ **determine whether the information qualifies for an exemption from disclosure in connection** with a request for information received by the Administrator under section 552 of title 5, United States Code;

"(ii) if ~~information available to the Administrator provides a basis that the requirements of section 552(b)(4) of title 5, United States Code, are no longer met;~~ **the Administrator has a reasonable basis to believe that the information does not qualify for protection against disclosure under subsection (a);** or

"(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

"(C) ACTION BY RECIPIENT.—If the Administrator makes a request under subparagraph (A) or (B), the recipient of the request shall—

"(i) reassert and substantiate or resubstantiate the claim; or

"(ii) withdraw the claim.

"(D) PERIOD OF PROTECTION.—Protection from disclosure of information subject to a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.

"(3) UNIQUE IDENTIFIER.—The Administrator shall—

"(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term; and

"(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

"(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to such a chemical substance during the period of protection from disclosure—

"(i) is made public; and

"(ii) identifies the chemical substance using the unique identifier; and

"(D) for each claim for protection of specific chemical identity that has been denied by the Administrator ~~on expiration of the period for appeal under subsection (g)(4), that has~~ **or** expired, or that has been withdrawn by the submitter, provide public access to the specific chemical identity clearly linked to all nonconfidential information received by the Administrator with respect to the chemical substance.

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"(g) Duties of Administrator.—

"(1) DETERMINATION.—

"(A) IN GENERAL.—Except as provided in subsection (b), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (d), and not later than 30 days after the receipt of a request for extension of a claim under subsection (f), review and approve, modify, or deny the claim or request.

"(B) **REASONS FOR DENIAL OR MODIFICATION.—If the Administrator denies or modifies a claim or request under subparagraph (A)** ~~Denial or modification.—~~

~~"(i) In general.—Except as provided in subsections (e) and (f),~~ the Administrator shall **provide to the person that submitted the claim or request** ~~deny a claim to protect a chemical identity from disclosure only if the person that has submitted the claim fails to meet the requirements of subsections (a) and (d).~~

~~"(ii) Reasons for denial or modification.—The Administrator shall provide to a person that has submitted a claim described in clause (i)~~ a written statement of the reasons for the denial or modification of the claim **or request**.

"(C) SUBSETS.—The Administrator shall—

"(i) except for claims described in subsection ~~(b)(7)~~**(b)(8)**, review all claims **or requests** under this section for the protection against disclosure of the specific identity of a chemical substance; and

"(ii) review a representative subset, comprising at least 25 percent, of all other claims **or requests** for protection against disclosure.

"(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim **or request** for protection against disclosure or extension under this section shall not be the basis for denial or elimination of a claim **or request** for protection against disclosure.

"(2) NOTIFICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (c), (e), and (f), if the Administrator denies or modifies a claim **or request** under paragraph (1), **intends to release information pursuant to subsection (e),** or promulgates a rule under section 6(d) establishing a ban or phase-out of a chemical substance, the Administrator shall notify, in writing and by certified mail, the person that submitted the claim of the intent of the Administrator to release the information.

"(B) RELEASE OF **INFORMATION.—Except** ~~information.—~~

~~"(i) In general.—Except~~ as provided in ~~clause (ii)~~ **subparagraph (C)**, the Administrator shall not release information under this subsection until the date that is 30 days after the date on which the person that submitted the request receives notification under subparagraph (A).

~~"(ii)~~**"(C)** EXCEPTIONS.—

Commented [A6]: It is confusing to refer to EPA "modifying," the claims of a 3rd party. EPA can't change the fact that some 3rd party claims something, but the intent here seems to be to allow EPA to approve a subset of the full claim. It would be clearer to refer to say: "approve, approve in part, or deny"

Commented [A7]: This specifies three bases on which information claimed CBI might be released, but misses an important basis: where EPA determines protection is not warranted at some point during the protection period.

Commented [A8]: Certified mail is a cumbersome form of notification.

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"~~(I)~~**"(i)** IN GENERAL.—For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim **or request** receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to health or the environment, in which case no prior notification shall be necessary.

"(ii) NOTIFICATION AS SOON AS PRACTICABLE.—For information under paragraphs (4) and (6) of subsection (e), the Administrator shall notify the person that submitted the information that the information has been disclosed as soon as practicable after disclosure of the information.

"(iii) NO NOTIFICATION REQUIRED.—Notification shall not be required—

"(I) for the disclosure of~~"(II) No notification.—For~~ information under paragraph (1), (2), ~~(6),~~(7), or (9) of subsection (e)~~, no prior notification shall be necessary.~~**; or**

"(II) for the disclosure of information for which—

"(aa) a notice under subsection (f)(1)(C)(i) was received; and

"(bb) no request was received by the Administrator on or before the date of expiration of the period for which protection from disclosure applies.

"(3) REBUTTABLE PRESUMPTION.—

"(A) IN GENERAL.—With respect to notifications provided by the Administrator ~~pursuant to subsection (e)(5)~~ **under paragraph (2) with respect to information pertaining to a chemical substance subject to a rule as described in subsection (c)(3)**, there shall be a rebuttable presumption that the public interest in disclosing confidential information related to a chemical substance subject to a rule promulgated under section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of the substance outweighs the proprietary interest in maintaining the protection from disclosure of that information.

"(B) REQUEST FOR NONDISCLOSURE.—A person that receives a notification under paragraph (2) with respect to the information described in subparagraph (A) may submit to the Administrator, before the date on which the information is to be released **pursuant to paragraph (2)(B)**, a request with supporting documentation describing why the person believes some or all of that information should not be disclosed.

"(C) DETERMINATION BY ADMINISTRATOR.—

"(i) IN GENERAL.—Not later than 30 days after the Administrator receives a request under subparagraph (B), the Administrator shall determine~~, at the discretion of the Administrator,~~ whether the documentation provided by the person making the request rebuts or does not rebut the presumption described in subparagraph (A), for all or a portion of the information that the person has

requested not be disclosed.

"(ii) OBJECTIVE.—The Administrator shall make the determination with the objective of ensuring that information relevant to protection of health and the environment is disclosed to the maximum extent practicable.

"(D) TIMING.—Not later than 30 days after making the determination described in subparagraph (C), the Administrator shall make public the information the Administrator has determined is not to be protected from disclosure.

"(E) NO TIMELY REQUEST RECEIVED.—If the Administrator does not receive, before the date on which the information described in subparagraph (A) is to be released **pursuant to paragraph (2)(B)**, a request pursuant to subparagraph (B), the Administrator shall promptly make public all of the information.

"(4) APPEALS.—

"(A) IN GENERAL.—If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released **pursuant to paragraph (2)(B)**, the person may bring an action to restrain disclosure of the information in—

"(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

"(ii) the United States District Court for the District of Columbia.

"(B) NO DISCLOSURE.—The Administrator shall not disclose any information that is the subject of an appeal under this section before the date on which the applicable court rules on an action under subparagraph (A).

"(5) ~~ADMINISTRATION.—IN CARRYING OUT THIS SUBSECTION, THE ADMINISTRATOR SHALL USE THE PROCEDURES DESCRIBED IN PART 2 OF TITLE 40, CODE OF FEDERAL REGULATIONS (OR SUCCESSOR REGULATIONS).~~ **REQUEST AND NOTIFICATION SYSTEM.—The Administrator, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop a request and notification system that allows for expedient and swift access to information disclosed pursuant to paragraphs (5) and (6) of subsection (e) in a format and language that is readily accessible and understandable.**

"(h) Criminal Penalty for Wrongful Disclosure.—

"(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

"(A) IN GENERAL.—Subject to paragraph (2), a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—

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"(i) by virtue of that employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a); and

"(ii) knowing that disclosure of that material is prohibited by subsection (a), willfully discloses the material in any manner to any person not entitled to receive that material.

"(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, making known of, or making available, information reported or otherwise obtained under this Act.

"(3) CONTRACTORS.—For purposes of this subsection, any contractor of the United States that is provided information in accordance with subsection (e)(2), including any employee of that contractor, shall be considered to be an employee of the United States.

"(i) Applicability.—

"(1) IN GENERAL.—Except as otherwise provided in this section, section 8, or any other applicable Federal law, the Administrator shall have no authority—

"(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information ~~submitted to~~ **reported to or otherwise obtained by** the Administrator under this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; or

"(B) to impose substantiation or resubstantiation requirements under this Act that are more extensive than those required under this section.

"(2) ~~PRIOR ACTIONS.—NOTHING~~ **ACTIONS PRIOR TO PROMULGATION OF RULES.—Nothing** in this Act prevents the Administrator from reviewing, requiring substantiation or resubstantiation for, or approving, modifying or denying any claim for the protection from disclosure of information before the effective date of such rules applicable to those claims as the Administrator may promulgate after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

Commented [A9]: It is confusing to refer to EPA "modifying," the claims of a 3rd party. EPA can't change the fact that some 3rd party claims something, but the intent here seems to be to allow EPA to approve a subset of the full claim. It would be clearer to refer to say: "approving, approving in part, or denying"

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/25/2015 7:57:06 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; Joseph, Avenel (Markey) [Avenel_Joseph@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on SNURs

Thanks - checking

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, June 25, 2015 3:56 PM
To: Kaiser, Sven-Erik
Cc: Joseph, Avenel (Markey)
Subject: TA request - SNURs

Hi Sven

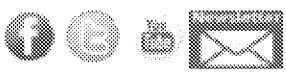
I'm looking for a couple of illustrative examples of SNURs that show how the section 5 considerations are typically described. It would be great to get one that describes the basis for removing the exemption for articles too.

Thanks
michal

(2) A determination by the Administrator that a use of a chemical substance is a significant new use with respect to which notification is required under paragraph (1) shall be made by a rule promulgated after a consideration of all relevant factors, including—
(A) the projected volume of manufacturing and processing of a chemical substance,
(B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,
(C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and
(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/25/2015 6:31:19 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; Joseph, Avenel (Markey) [Avenel_Joseph@markey.senate.gov]
Subject: Sen. Markey TSCA TA on co-enforcement

Michal,
Thanks for the technical assistance request. We'll get back to you with a response. Please let me know if any additional questions. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, June 25, 2015 1:29 PM
To: Kaiser, Sven-Erik
Cc: Joseph, Avenel (Markey); Freedhoff, Michal (Markey)
Subject: TSCA TA - co-enforcement

Hi Sven

I have a question for you on this slightly modified version of the House co-enforcement penalty language. In a case in which a chemical company was doing the same bad thing in, say, 10 States, would each state's enforcement activities be a separate "specific violation" or could they all be considered to be the SAME specific violation under this language? My sense is that since each state would be enforcing something that was occurring in their own states, each violation would be different, but someone flagged this as a concern for me and I figured I would ask.

Thanks
michal

If a State or the Administrator has assessed a penalty for a specific violation, the Administrator or the State may not subsequently assess a penalty for that violation in an amount that would cause the total of the penalties assessed for the violation by the State and the Administrator combined to exceed the maximum amount that may be assessed for that violation by the Administrator under section 16.''

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
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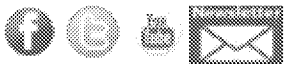
Washington, DC 20510
202-224-2742

Connect with Senator Markey



Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 11/25/2015 5:00:38 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: questions on safety standard

Got it- will get a response. Thanks,
Sven

On Nov 25, 2015, at 11:57 AM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

I have questions about the manner in which the safety standard intersects with section 6.

Definition of safety standard:

> "(16) SAFETY STANDARD.—The term 'safety standard' means a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of injury to health or the environment will result from exposure to a chemical substance under the conditions of use, including no unreasonable risk of injury to—
>
> "(A) the general population; or
>
> "(B) any potentially exposed or susceptible population that the Administrator has identified as relevant to the safety assessment and safety determination for a chemical substance.".

As a matter of policy, we are telling EPA to figure out how to ensure a chemical doesn't harm people, and additionally telling EPA to do so without considering costs. If EPA determines that the manner in which a chemical is or will be used cannot ensure that no harm will occur, EPA is then told to consider costs as it writes a regulation to determine that the chemical, in the manner in which it is or will be used, will not harm people.

Some questions have arisen:

1) <!--[if !supportLists]--><!--[endif]-->How can Congress tell EPA it must require safety in a manner that DOES consider costs, after being told it has to ENSURE safety WITHOUT considering costs?
2) <!--[if !supportLists]--><!--[endif]-->Is there an inconsistency or conflict associated with the use of the word "ensure" in the safety standard?
3) <!--[if !supportLists]--><!--[endif]-->Is there an inconsistency or conflict associated with saying EPA can't consider costs in the safety standard, and THEN telling EPA to consider costs when it decides how to ensure that the chemical meets the safety standard (which in turn cannot consider costs)?
4) <!--[if !supportLists]--><!--[endif]-->If EPA is told that a safety standard has to ENSURE that no harm occurs due to a chemical, and then someone gets cancer from that chemical, could the person sue EPA for failing to "ENSURE" that they did not get cancer (or does the word "unreasonable" include within it enough subjectivity to ensure that litigation would be about the sufficiency of what EPA said was unreasonable as opposed to an absolute finding that someone was harmed)?

Thanks very much

Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
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202-224-2742

Connect with Senator Markey
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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 11/25/2015 4:54:30 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA request on Preemption

I was on for a while, had to jump so I wasn't sure on followup assignments. Thanks

On Nov 25, 2015, at 11:53 AM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Yes – typing them up now.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, November 25, 2015 11:53 AM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA request on Preemption

Understood. Are you going to send any additional requests following the call? Thanks,
Sven

On Nov 25, 2015, at 11:42 AM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Sorry, meaning I don't need anything written on this....

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
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From: Freedhoff, Michal (Markey)
Sent: Wednesday, November 25, 2015 11:42 AM

To: 'Kaiser, Sven-Erik'
Subject: RE: Sen. Markey TSCA TA request on Preemption

We covered this. Thanks.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, November 25, 2015 8:26 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request on Preemption

Michal, got it. Thanks,
Sven

On Nov 25, 2015, at 7:21 AM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

In both the House and Senate TSCA bills (and in underlying TSCA) there is some degree of section 5 preemption, w Senate bill being the least preemptive and House bill being the most.

I'd like to understand, as a legal matter, what happens to a new chemical once it is no longer a new chemical and goes on the inventory because it is being manufactured.

In EPA's views, do the effects of section 5 preemption disappear when the chemical becomes an "existing chemical" such that if, 20 years after it goes on the market and risks about it become more known, a state could regulate it subject to whatever section 6 preemption exists?

If the response to that question is different for any of House, Senate or underlying TSCA, I'd also appreciate an explanation as to where in the text those differences arise.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 11/25/2015 12:10:19 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on PBT

Michal, got it. Will get a response as soon as possible. Please let me know if any additional questions. Thanks,
Sven

On Nov 24, 2015, at 10:11 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

Question for you – section 5 PBT language in S 697 require EPA to know whether a new chemical scores high for P or B and high or moderate for the other in order to make it subject to the exposure reduction standard. Would this be a null set provision – how would EPA know that a chemical was P, B, or T, let alone the degree to which it had those properties, if it was new?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 11/24/2015 9:20:06 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; 'dimitri_Karakitsos@epw.senate.gov' [dimitri_Karakitsos@epw.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Sen. Markey TSCA TA on Preservation Clauses
Attachments: Markey.TSCA TA.Preservation Clauses.docx

Michal,
The attached document responds to the technical assistance request on TSCA preservation clauses. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, November 23, 2015 9:32 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Karakitsos, Dimitri (EPW) <Dimitri_Karakitsos@epw.senate.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Subject: question

Sven

S 697 contains a number of provisions intended to clarify that as EPA implements a newly re-authorized TSCA, it can continue to do what it is currently doing under old TSCA, or otherwise incorporate old EPA policies etc as appropriate into the new versions. I've pasted some excerpts below. We have heard from some that some or all of this language is unnecessary, and that there would be no reason why EPA couldn't or wouldn't do all of these things on its own. Can you please provide EPA's views on this question, both generally and with specific consideration of this unique circumstance of a fairly comprehensive re-write of a statute that is in large part nonfunctional?

Thanks
Michal

"(d) Existing EPA Policies, Procedures, and Guidance.—The policies, procedures, and guidance described in subsection (b) shall incorporate~~, as appropriate, existing relevant hazard, exposure, and risk assessment guidelines and methodologies, data evaluation and quality criteria, testing methodologies, and other relevant guidelines and policies of the Environmental Protection Agency.~~ **existing relevant policies, procedures, and guidance, as appropriate and consistent with this Act.**

"(b) Prior Actions and Notice of Existing Information.—

"(1) PRIOR-INITIATED ASSESSMENTS.—

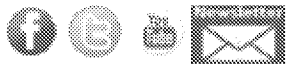
"(A) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a safety assessment or safety determination regarding a chemical substance, or from continuing or completing such a safety assessment or safety determination ~~that was initiated before the date of enactment of the~~

~~Frank R. Lautenberg Chemical Safety for the 21st Century Act~~, prior to the effective date of the policies ~~and~~**,** procedures**, and guidance** required to be established by the Administrator under section 3A or 4A.

"(B) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—As policies and procedures under section 3A and 4A are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing safety assessments and safety determinations.

"(2) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—Nothing in this Act requires the Administrator to revise or withdraw a completed safety assessment, safety determination, or rule solely because the action was completed prior to the completion of a policy or procedure established under section 3A or 4A, and the validity of a completed assessment, determination, or rule shall not be determined based on the content of such a policy or procedure.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742



This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and comments.

Request: S 697 contains a number of provisions intended to clarify that as EPA implements a newly re-authorized TSCA, it can continue to do what it is currently doing under old TSCA, or otherwise incorporate old EPA policies etc as appropriate into the new versions. I've pasted some excerpts below. We have heard from some that some or all of this language is unnecessary, and that there would be no reason why EPA couldn't or wouldn't do all of these things on its own. Can you please provide EPA's views on this question, both generally and with specific consideration of this unique circumstance of a fairly comprehensive re-write of a statute that is in large part nonfunctional?

1. **General technical assistance**

It is difficult to comment on the entire category of "provisions intended to clarify . . . [that EPA] can continue to do what it is currently doing," because it is not clear to us which specific provisions of the bill you are referencing. To illustrate this point, note that the two particular passages cited as examples of this category are actually fairly dissimilar in their impact. The impact of retaining or deleting particular passages is best analyzed on a passage-specific basis.

Furthermore, note that the legal impact of deleting a particular passage (present in the committee draft) is potentially different from the legal impact of having never included the passages in the first place. This is because subsequent interpreters of the bill may infer that the authors of the bill were actually repudiating whatever principle the deleted language stood for. If you do not intend to repudiate the underling objective of a particular passage, but simply feel that the language is duplicative of existing law and should be deleted in the interest of concision, it would be helpful to include an explanation to that effect in the legislative history for the bill. This will help to avoid subsequent misinterpretation of the legislation.

2. **Technical assistance regarding first cited passage**

***

"(d) Existing EPA Policies, Procedures, and Guidance.—The policies, procedures, and guidance described in subsection (b) shall incorporate, as appropriate, existing relevant hazard, exposure, and risk assessment guidelines and methodologies, data evaluation and quality criteria, testing methodologies, and other relevant guidelines and policies of the Environmental Protection Agency. ***existing relevant policies, procedures, and guidance, as appropriate and consistent with this Act.****"*

***

Assuming that there is appropriate legislative history to explain the deletion (i.e., to clarify that deletion of this text does not reflect Congress' view that EPA should re-develop all policies from scratch), deleting this language would likely have little or no impact on the implementation of TSCA.

This is because the passage doesn't actually purport to give EPA any additional authority and, to the extent it establishes any EPA duty, the duty is subject to significant qualification ("appropriate and consistent").

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and comments.

3. **Technical assistance regarding second cited passage**

***

"(b) Prior Actions and Notice of Existing Information.—

"(1) Prior-initiated assessments.—

"(A) In general.—Nothing in this Act prevents the Administrator from initiating a safety assessment or safety determination regarding a chemical substance, or from continuing or completing such a safety assessment or safety determination that was initiated before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, prior to the effective date of the policies and, procedures, ***and guidance*** *required to be established by the Administrator under section 3A or 4A.*

"(B) Integration of prior policies and procedures.—As policies and procedures under section 3A and 4A are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing safety assessments and safety determinations.

"(2) Actions completed prior to completion of policies and procedures.—Nothing in this Act requires the Administrator to revise or withdraw a completed safety assessment, safety determination, or rule solely because the action was completed prior to the completion of a policy or procedure established under section 3A or 4A, and the validity of a completed assessment, determination, or rule shall not be determined based on the content of such a policy or procedure."

***

These passages are not merely restating principles that would be otherwise self-evident. Rather, they reflect a substantive counterbalance to the bill's detailed requirements that EPA develop various guidance and procedural documents in the early years of implementation, by making clear that the development of the procedural documents can proceed in parallel with substantive implementation. In so doing, they provide clarity on a point that might not otherwise be clear, and they may remove a potential stakeholders' incentive to litigate and otherwise delay the issuance of preliminary procedural documents simply as a means to delay the start of substantive implementation of the new TSCA program.

Specifically:

- (b)(1)(A) addresses a potential legal challenge asserting that EPA cannot start or continue a safety assessment, based on delays in related implementation materials
- (b)(1)(B) addresses a potential legal challenge asserting that a safety determination is necessarily invalid because it is inconsistent in certain respects with implementation/guidance materials that were not finalized until after the determination was already underway.
- (b)(2) addresses a potential legal challenges asserting that the finalization of a procedural document automatically triggers an obligation to vacate and re-do previously completed safety determinations.

- (b)(2) also addresses potential legal challenges to policy and procedural documents, which might be initiated in order to collaterally attack all the substantive decisions that were previously issued using those procedures.

4. Technical assistance regarding two other specific passages, not cited but within the scope of the general request.

We are aware of at least two other substantive provisions that discuss the relationship between the bill and existing TSCA, and that we do not believe are redundant/superfluous.

§18(d)(2):

***

"(2) APPLICABILITY TO CERTAIN RULES OR ORDERS.—Notwithstanding subsection (e)—
"(A) nothing in this section shall be construed as modifying the effect under this section, as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, of any rule or order promulgated or issued under this Act prior to that effective date; and
"(B) with respect to a chemical substance or mixture for which any rule or order was promulgated or issued under section 6 prior to the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act with regards to manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance, this section (as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act) shall govern the preemptive effect of any rule or order that is promulgated or issued respecting such chemical substance or mixture under section 6 of this Act after that effective date, unless the latter rule or order is with respect to a chemical substance or mixture containing a chemical substance and follows a designation of that chemical substance as a high-priority substance under subsection (b) or (c) of section 4A(b) or as an additional priority for safety assessment and safety determination under section 4A(c).

***

This passage is substantive because it provides that the existing TSCA preemption provisions that are stricken from the law apply to certain EPA actions. (B) in particular is substantive, because it applies the existing TSCA preemption provisions to certain future EPA actions.

§ 26(h):

***

"(h) Prior Actions.—Nothing in this Act eliminates, modifies, or withdraws any rule promulgated, order issued, or exemption established pursuant to this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and comments.

***

The passage is substantive because it eliminates any ambiguity about whether the major structural revisions to TSCA impliedly repeal significant EPA regulations issued under prior TSCA. For example, numerous SNURs that have been issued, PMN regulations, Chemical Data Reporting regulations, PCB regulations, etc.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/22/2015 9:33:04 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: RE: SEPW TSCA TA Request on Agreements for Testing

Ok - thanks

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, June 22, 2015 5:33 PM
To: Kaiser, Sven-Erik
Subject: RE: SEPW TSCA TA Request on Agreements for Testing

These folks came in and asked for EPA to clarify what a small business is, that it's been years upon years since EPA updated it and now it captures too many businesses.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, June 22, 2015 5:30 PM
To: Black, Jonathan (Tom Udall)
Subject: RE: SEPW TSCA TA Request on Agreements for Testing

Jonathan,
We'll be prepared. Do you know what the angle is on the SBA question? Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, June 22, 2015 4:57 PM
To: Kaiser, Sven-Erik
Subject: RE: SEPW TSCA TA Request on Agreements for Testing

Thanks. we'll have the usual suspects on the call. give me a buzz if you want me to run through the list. Otherwise, talk to you tomorrow. Thanks!
224-6722

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, June 22, 2015 4:52 PM

To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW)
Cc: Zipkin, Adam (Booker)
Subject: RE: SEPW TSCA TA Request on Agreements for Testing

Got it – will pass along. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, June 22, 2015 4:51 PM
To: Kaiser, Sven-Erik; Karakitsos, Dimitri (EPW)
Cc: Zipkin, Adam (Booker)
Subject: RE: SEPW TSCA TA Request on Agreements for Testing

Hi! Another topic that may also come up tomorrow: we would also like to discuss the existing TSCA Section 8(a)(3)(B) requirement that the Administrator consult with the SBA Administrator to propose standards for determining which manufacturers and processors qualify as small manufacturers and processors

---

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, June 22, 2015 1:48 PM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TSCA TA Request on Agreements for Testing

Great – for the call on Tues, June 23 at 10 am, please call 866-299-3188, code 202-566-2753#. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, June 22, 2015 1:47 PM
To: Kaiser, Sven-Erik; Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TSCA TA Request on Agreements for Testing

Can we do tomorrow at 10am? Do you have a number we can call into?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, June 22, 2015 1:24 PM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TSCA TA Request on Agreements for Testing

Jonathan and Dimitri,
Availability for a call on testing:
- Tues, June 23 from 10-12

- Weds, June 24 at 1

Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, June 22, 2015 11:56 AM
To: Kaiser, Sven-Erik
Cc: Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TSCA TA Request on Agreements for Testing

Sorry, yes, I meant this week.

We could do this on the phone.

We're nearing completion on the full package, too, and will probably want to sit with you as to walk through them all. not sure if we will be able to do that this week or next week.

What is your availability tomorrow to discuss consent agreements?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, June 22, 2015 11:54 AM
To: Black, Jonathan (Tom Udall)
Cc: Karakitsos, Dimitri (EPW)
Subject: SEPW TSCA TA Request on Agreements for Testing

Jonathan and Dimitri – we'll be glad to talk about agreements for testing. We're you thinking this week (week of June 22) or next week (week of June 29). Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, June 22, 2015 11:48 AM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW)
Subject: Sec 12 edits revised for TA 6-18-15

Sven,

Thank you for the recent TA you provided. We have a follow-up request on two of the issues.

1. Section 12, Exports. We agree with your points in the prior TA and have struck the references to sections 5 and 6 and to the safety standard. However, the intent all along has been to apply the exceptions both to new chemicals that are found likely to present an unreasonable risk in the U.S., and to existing chemicals that are found present or will present an unreasonable risk. Hence, the language below retains the two subparagraphs; see attachment. Subparagraph (A) uses the term "new chemical substance" which is defined in TSCA, while (B) refers more generally to chemical substances. Does this work?
2. We have a lot of questions regarding consent agreements for testing in relation to other provisions of the bill, including citizen civil actions. We would like to find a time to meet next week to discuss this issue with you. Would you be able to do so?

Thank you …

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 11/24/2015 9:07:27 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA Request on "Designed By"
Attachments: Markey.TSCA TA on Replacement Parts.docx

Michal,
The attached technical assistance responds to your request on "replacement parts" and "designed by" language. In addition, we provided an additional response on the earlier enzyme system question. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, November 23, 2015 6:41 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Subject: Re: Sen. Markey TSCA TA Request on "Designed By"

Would add to this - does epa have a definition of "replacement part" that I can see? Would it include, for example, a seat cover for a couch, or a piece that replaces a part of a broken toy?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Thursday, November 19, 2015 7:37 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on "Designed By"

Got it. Also, there was a glitch in the nomenclature TA. We'll try to get it tomorrow, may take an extra day or two.
Thanks,
Sven

On Nov 19, 2015, at 7:19 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

This one is on "designed by" in House bill.

I'd like to try to figure out 2 options for this.

1) Something that says replacement parts for articles **designed by** the effective date that meet some criteria are exempted from the rule (for example, that it goes into a product that has a longer design cycle, that would be difficult to re-design, etc – the things that would capture the part of the car brakes or plane engine that is hard to re-design, but not the car or plane seat covers covered in flame retardant chemicals that should be easy to redesign).

2) Something that puts the "designed by" language into the exemption part of Section 6 in much the same way, instead of option 1 where EPA de facto posture is to HAVE to exempt all replacement parts that meet criteria, change so presumption is that EPA CAN exempt if criteria are met.

I'd like this by early next week if at all possible.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
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255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and comments.

A. Request to draft two modifications to HR 2576 regarding replacement parts:

1. Something that says replacement parts for articles **designed by** the effective date that meet some criteria are exempted from the rule (for example, that it goes into a product that has a longer design cycle, that would be difficult to re-design, etc – the things that would capture the part of the car brakes or plane engine that is hard to re-design, but not the car or plane seat covers covered in flame retardant chemicals that should be easy to redesign).
2. Something that puts the "designed by" language into the exemption part of Section 6 in much the same way, instead of option 1 where EPA de facto posture is to HAVE to exempt all replacement parts that meet criteria, change so presumption is that EPA CAN exempt if criteria are met.

Following is our suggested drafting, with redline strikeout based on existing bill text. We have included language that thought captured your suggestion:

1. Retain the replacement parts language where it appears in the bill (section 6(c)(1)(D)), but add the following text:

   "Exempt replacement parts that would be impracticable to redesign or replace without redesigning the articles of which they are components, and that are designed prior to the effective date of ~~publication in the Federal Register of~~ the rule, unless the Administrator finds such replacement parts contribute significantly to the identified risk, including identified risk to identified potentially exposed subpopulations."

2. Delete section 6(c)(1)(D) and add, in the subsection on critical use exemptions (section 6(h) the following new paragraph (6(C)(1)(D)), as an independent basis for exemption:

   "The requirement applies to~~Exempt~~ replacement parts that would be impracticable to redesign or replace without redesigning the articles of which they are components, and that are designed prior to the effective ~~date of publication in the Federal Register~~ of the rule, unless the Administrator finds such replacement parts contribute significantly to the identified risk, including identified risk to identified potentially exposed subpopulations."

You also asked whether EPA has a definition of "replacement parts". To our knowledge, EPA does not have such a definition.

****

B. Question -- does EPA currently utilize the following nomenclature system in the same way it uses the soap one, Portland cement, etc: Enzyme Nomenclature System, Recommendations of the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology on the Nomenclature and Classification of

Enzymes by the Reactions they Catalyse, published in Enzyme Nomenclature 1992 (ISBN 0-12-227164-5), as supplemented? And, is it appropriate to add this to the list, if one has such a list in the statute in the first place?

EPA does not utilize this system, and the agency has some questions about the potentially lengthy time required to develop names under this system. If there is a desire to have EPA work to develop a nomenclature system for enzymes, the following text could be added to S. 697 as section 8(b)(3)(A)((iv) of TSCA: "develop a nomenclature system for enzymes by [INSERT DATE]".

****

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 11/24/2015 2:35:11 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Sen. Markey TSCA TA on existing TSCA Preservation

Michal,
Thank you for the request. I'll check with folks and get back to you with a response. Timeframe? Best,
Sven

On Nov 23, 2015, at 9:32 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

S 697 contains a number of provisions intended to clarify that as EPA implements a newly re-authorized TSCA, it can continue to do what it is currently doing under old TSCA, or otherwise incorporate old EPA policies etc as appropriate into the new versions. I've pasted some excerpts below. We have heard from some that some or all of this language is unnecessary, and that there would be no reason why EPA couldn't or wouldn't do all of these things on its own. Can you please provide EPA's views on this question, both generally and with specific consideration of this unique circumstance of a fairly comprehensive re-write of a statute that is in large part nonfunctional?

Thanks
Michal

"(d) Existing EPA Policies, Procedures, and Guidance.—The policies, procedures, and guidance described in subsection (b) shall incorporate~~, as appropriate, existing relevant hazard, exposure, and risk assessment guidelines and methodologies, data evaluation and quality criteria, testing methodologies, and other relevant guidelines and policies of the Environmental Protection Agency.~~ **existing relevant policies, procedures, and guidance, as appropriate and consistent with this Act.**

"(b) Prior Actions and Notice of Existing Information.—

"(1) PRIOR-INITIATED ASSESSMENTS.—

"(A) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a safety assessment or safety determination regarding a chemical substance, or from continuing or completing such a safety assessment or safety determination ~~that was initiated before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act~~, prior to the effective date of the policies ~~and~~**,** procedures**, and guidance** required to be established by the Administrator under section 3A or 4A.

"(B) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—As policies and procedures under section 3A and 4A are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing safety assessments and safety determinations.

"(2) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—Nothing in this Act requires the Administrator to revise or withdraw a completed safety assessment, safety determination, or rule solely because the action was completed prior to the completion of a policy or procedure established under section 3A or 4A, and the validity of a completed assessment, determination, or rule shall not be determined based on the content of such a policy or procedure.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 11/23/2015 11:26:45 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA Request on "Designed By"

On it

On Nov 23, 2015, at 6:00 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Hi Sven –

I need all of this by tomorrow afternoon – thanks very much.

Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, November 23, 2015 7:20 AM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA Request on "Designed By"

Michal, Got it, checking. Will add to the previous TA request. Thanks,
Sven

On Nov 23, 2015, at 6:41 AM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Would add to this - does epa have a definition of "replacement part" that I can see? Would it include, for example, a seat cover for a couch, or a piece that replaces a part of a broken toy?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Thursday, November 19, 2015 7:37 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on "Designed By"

Got it. Also, there was a glitch in the nomenclature TA. We'll try to get it tomorrow, may take an extra day or two.
Thanks,
Sven

On Nov 19, 2015, at 7:19 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

This one is on "designed by" in House bill.

I'd like to try to figure out 2 options for this.

1) Something that says replacement parts for articles **designed by** the effective date that meet some criteria are exempted from the rule (for example, that it goes into a product that has a longer design cycle, that would be difficult to re-design, etc – the things that would capture the part of the car brakes or plane engine that is hard to re-design, but not the car or plane seat covers covered in flame retardant chemicals that should be easy to redesign).
2) Something that puts the "designed by" language into the exemption part of Section 6 in much the same way, instead of option 1 where EPA de facto posture is to HAVE to exempt all replacement parts that meet criteria, change so presumption is that EPA CAN exempt if criteria are met.

I'd like this by early next week if at all possible.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/22/2015 3:48:37 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
CC: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
Subject: RE: Sec 12 edits revised for TA 6-18-15

Thanks - checking

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, June 22, 2015 11:48 AM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW)
Subject: Sec 12 edits revised for TA 6-18-15

Sven,

Thank you for the recent TA you provided. We have a follow-up request on two of the issues.

1. Section 12, Exports. We agree with your points in the prior TA and have struck the references to sections 5 and 6 and to the safety standard. However, the intent all along has been to apply the exceptions both to new chemicals that are found likely to present an unreasonable risk in the U.S., and to existing chemicals that are found present or will present an unreasonable risk. Hence, the language below retains the two subparagraphs; see attachment. Subparagraph (A) uses the term "new chemical substance" which is defined in TSCA, while (B) refers more generally to chemical substances. Does this work?
2. We have a lot of questions regarding consent agreements for testing in relation to other provisions of the bill, including citizen civil actions. We would like to find a time to meet next week to discuss this issue with you. Would you be able to do so?

Thank you …

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/19/2015 7:07:12 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on "sound" science and SDWA

Michal,
Following up on your request, the Safe Drinking Water Act requires that, in setting new drinking water standards, EPA "shall use (i) the best available, peer reviewed science and supporting studies conducted in accordance with sound and objective scientific practices" (SDWA Section 1412(b)(3)(A)).

EPA has been sued based on this language, but the "sound and objective scientific practices" language has not figured into the courts' opinions, and the judgment of attorneys in the counsel's office in EPA is that the language was not a significant factor in the cases. As far as we know, "sound" is not used to modify science or scientific practices or processes in other EPA statutes or regulations.

You also asked about the language regarding "best available, peer-reviewed science". While this is not the language that appears in S 697, we can look into whether that SDWA language has been specifically raised in litigation. The person in the counsel's office we need to ask is not available today, please let me know if you would like us to follow up on that.

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, June 18, 2015 2:53 PM
To: Kaiser, Sven-Erik
Cc: Freedhoff, Michal (Markey)
Subject: FW: "sound" science - this is from the Safe Drinking Water Act

Sven - forgot this follow-up to see if there are other examples like this you guys flagged on the call yesterday, and whether the language below has been subject to litigation?

Thanks
Michal

(3) RISK ASSESSMENT, MANAGEMENT, AND COMMUNICATION.—
(A) USE OF SCIENCE IN DECISIONMAKING.—In carrying out this section, and, to the degree that an Agency action is based on science, the Administrator shall use—
(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and
(ii) data collected by accepted methods or best available methods (if the reliability of the method and

the nature of the decision justifies use of the data).

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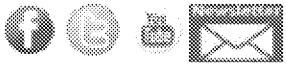
Connect with Senator Markey



Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/19/2015 6:13:04 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: SEPW TSCA TA on June 8 version

Jonathan,
In addition to the broken references, we have the following additional technical assistance on the June 8 version:

P 22 line 18: "this section" was changed to "subsections (a)(2) and (b)(3)" in the 4A provisions dealing with the balance of high priority and additional priority chemicals. This change is incorrect, because the additional priority chemicals are not chemicals designated to undergo safety assessments and determinations under these subsections, which apply only to high priority substances. "[S]ubstances designated to undergo safety assessments and safety determinations under this section" is a reference to the whole of all priority designations, which sets up the next statement, which is that the portion "pursuant to paragraph (1)" needs to be between 25% and 30%.

P 43 line 5: Section 9(a), as amended, requires EPA to "initiate action under section 6(d) or 7" if the other agency does not respond in a way that blocks EPA action. This probably should say "initiate action under section 6(d), and as appropriate under section 7". Section 6(d) action is mandatory, per section 6(a). The drafting suggests that a section 7 action might satisfy an otherwise extant obligation to proceed under section 6(d).

P 43: In the export section (12), in lines 29-35, the retention of references to section 5 and 6 will create confusion, since there are no provisions under sections 5 and 6 under which EPA would make an assessment of whether the exported portion of a chemical will present an unreasonable risk in the US. Rather, such a determination would be made under section 12, for the purpose of section 12 only. Per our earlier TA, we recommend dropping those lines, and any reference to section 5 or 6, and substituting the following: "will present an unreasonable risk of injury to health within the United States to or the environment of the United States, without taking into account cost or other non-risk factors".

P 66: You have made positive safety determinations (a type of order) subject to the time limited judicial review in section 19(a)(1)(A), but there are two lingering references to "rule" in existing 19(a)(1)(A) that should be changed to "rule or order", as a conforming change. Similar conforming changes should be made to 19(a)(2), where "rulemaking" and "rule", but not "order", are referenced. Thus, change "the filing of the rulemaking record of proceedings on which the Administrator based the rule being reviewed" to "the filing of the record of proceedings on which the Administrator based the rule or order being reviewed"

p 66: In addition, you used the word "chapter" to describe the rules subject to review under 19(a)(1)(A) and "title" to describe the orders subject to review under 19(a)(1)(B). Is a difference intended? (We also note that, as amended, section 19(a)(1)(A) covers all rules "under this chapter", and also rules under title II or IV. Does the "chapter" refer to all of TSCA (in which case the reference to titles II and IV are not needed), or only subchapter I? We are not expert in the use of the terms "title" and "chapter" in bills and how they are codified into enacted legislation, and we assume leg counsel will consider this.)

This technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Kaiser, Sven-Erik
Sent: Wednesday, June 10, 2015 4:51 PM
To: 'Black, Jonathan (Tom Udall)'
Subject: SEPW TSCA TA on broken references

Jonathan,
Thank you for the request to look at the latest version of the bill, Although we haven't done a complete review, we spotted a technical problem that could be significant so we wanted to get it to you right away.

- There is a broken cross reference in section 26(b)(3)(D)… (page 69) it should say "notwithstanding (B)" instead of "notwithstanding (C)." (The $18 million cap paragraph is now called paragraph (B) rather than paragraph (C)). This error has the potential to confound EPA's authority to collect fees beyond the $18 million cap, for industry sponsored chemicals.

- Also, another broken cross reference from renumbering - 3A(d) refers to subsection (b) which was renumbered as (a).

Please let me know if any questions. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/19/2015 6:02:02 PM
To: 'Cohen, Jacqueline' [jackie.cohen@mail.house.gov]
Subject: HEC TSCA TA on preemption - correction
Attachments: TECHNICAL ASSISTANCE ON MAY 12 HOUSE DRAFT JUNE 1.docx

Jacqueline,
In EPA's previous TA on the bill, we indicated that due to the drafting of section 18(a)(2)(C), PCB rules would have no preemptive effect. We were wrong about that, because section 18(e) specifies that the bill does not change the preemptive effect of action taken under section 6(e). So, please ignore that TA -- sorry for any confusion. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/16/2015 10:42:17 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; Joseph, Avenel (Markey) [Avenel_Joseph@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request- Sound Science
Attachments: epa-principles-of-scientific-integrity.pdf; peer_review_handbook_2012.pdf; rchandbk.pdf; ECOTXTBX.PDF

Michal,
This responds to your request for technical assistance on "sound science." EPA does not believe the phrase "sound science" is used in any EPA statutes, and we are not aware of case law construing the phrase. We note that the phrase is not used in the Senate bill either (or in the House bill). It appears that the closest language is in section 18(f)(1)(D) of the Senate bill as voted out of committee, which allows for discretionary preemption waivers for state laws that, among other things, are "consistent with sound objective scientific practices."

Attached are documents laying out key policies underlying EPA's scientific processes:
Principles of Scientific Integrity
Peer Review Handbook
The Risk Characterization Handbook
Guidances for Ecological Risk Assessment

The technical assistance is intended for use only by the requester. The technical assistance doesn not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey)
Sent: Monday, June 8, 2015 10:38 AM
To: Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)
Cc: Freedhoff, Michal (Markey); Joseph, Avenel (Markey)
Subject: TSCA - TA request on "sound" science

Sven

Is "sound" science used in any other EPA statutes? Does the term have an understood meaning either through regulation or case law?

Thanks
michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey

255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/16/2015 5:50:00 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]; Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
Subject: SEPW TSCA TA requests on Exports, Penalties, Citizen's Civil Actions
Attachments: Sec. 12 edits for EPA TA - (6-11-15).docx; Sec. 16 edits for EPA TA - (6-11-15).docx; Sec. 19 edits for EPA TA - (6-11-15).docx

Jonathan and Dimitri,
Please see EPA's technical assistance in response to your questions.

1. Section 13, Exports (see attachment): The change you suggested earlier has been inserted into paragraphs (2)(A) and (B).

Question: Is further clarification needed as to whether those determinations are:
a. limited to risks in the U.S., and
b. limited to the manufacture, processing, and distribution in commerce of the exported portion of the chemical substance?
Possible text additions to address each of these are shown on lines 4-5 and 6 and 7.

EPA Response: Instead of the changes you suggest, EPA recommends, per our earlier TA, deleting subparagraphs A and B and any reference to sections 5 and 6, in in their place inserting: "will present an unreasonable risk of injury to health within the United States to or the environment of the United States, without taking into account cost or other non-risk factors". The retention of references to sections 5 and 6 will create confusion, since there are no provisions under sections 5 and 6 under which EPA would make an assessment of whether the exported portion of a chemical will present an unreasonable risk in the US. This is a determination that EPA would make under section 12, solely for the purpose of section 12. The suggested language would essentially leave the relevant text of current TSCA section 12(a) unchanged (exact for clarifying no consideration of cost), and we don't see that any change in the bill necessitate additional changes to 12(a). If the suggested language is accepted, EPA does not think it's necessary to specify that the determination applies only to the exported portion. This is not specified in existing TSCA 12(a), and we think that concept is implicit in the provision.

2. Section 16, Penalties (see attachment): Per your earlier TA, we have incorporated verbatim language from the Clean Air Act section 113(c)(5)(B) regarding "knowledge of imminent danger or injury," "affirmative defenses," and "defenses," as well as relevant definitions. This represents a lot of new text, however.

Question: Is there a way to incorporate all of this by reference?

EPA Response: EPA suggests using the following language:

"(C) Incorporation of Corresponding Provisions.--The provisions of 42 U.S.C. 7413(5)(B)-(F) also apply to the prosecution of a violation under this paragraph."

3. Section 19, Citizen's Civil Actions (see attachment): Per your earlier TA, we have expanded the section 4 actions subject to this section to include testing consent agreements and test orders, as well as test rules.

Questions:
a. On the one hand, this change conforms the section to encompass all of the new section 4 authorities. On the other hand, does it represent an expansion beyond current TSCA by subjecting consent agreements (which EPA uses sometimes under current TSCA) to citizen's civil actions? [There are competing views on this: a concern about expanding the scope of this section vs. ensuring that the adequacy of testing using any of the available instruments is able to be challenged by any party (consent agreements presumably would not be

challenged by industry, as the relevant company will have already consented, but if they are not challengeable by others, that raises a concern).]

EPA Response: Whether consent agreements would be subject to section 20 under TSCA is unclear -- because EPA does not have express authority under TSCA to enter consent agreements and they are not referenced in the state. This is an issue EPA has not taken a position on. Note that the issue in section 20 is not whether a consent agreement can be challenged, as your question suggests. The issue is whether the requirements of a consent agreement could be enforced by a citizen.

b. Under what circumstances would EPA expect to use a testing consent agreement rather than a test order? How would that decision potentially be affected if it were the case that only the latter action was subject to citizens' civil actions?

EPA Response: It is difficult to predict all of the factors that EPA might consider going forward in deciding whether to require testing via consent agreement or order. In general, though, it's likely that EPA would select the most efficient and timely vehicle for requiring the testing. EPA does not expect that the availability of citizen suit would factor into EPA's choice of testing vehicle.

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Thursday, June 11, 2015 1:53 PM
To: Kaiser, Sven-Erik
Cc: Karakitsos, Dimitri (EPW); Black, Jonathan (Tom Udall)
Subject: Additional TA requests | Exports - Penalties - Citizen's Civil Actions
Importance: High

Sven, we have been diligently working through your TA:

I think we've made a lot of progress, but now there are three areas we still need some attention.

1. Section 13, Exports (see attachment): The change you suggested earlier has been inserted into paragraphs (2)(A) and (B).

   Question: Is further clarification needed as to whether those determinations are:
   a. limited to risks in the U.S., and
   b. limited to the manufacture, processing, and distribution in commerce of the exported portion of the chemical substance?

   Possible text additions to address each of these are shown on lines 4-5 and 6 and 7.

2. Section 16, Penalties (see attachment): Per your earlier TA, we have incorporated verbatim language from the Clean Air Act section 113(c)(5)(B) regarding "knowledge of imminent danger or injury," "affirmative defenses," and "defenses," as well as relevant definitions. **This represents a lot of new text, however.**

Question: Is there a way to incorporate all of this by reference?

3. Section 19, Citizen's Civil Actions (see attachment): Per your earlier TA, we have expanded the section 4 actions subject to this section to include testing consent agreements and test orders, as well as test rules.

   Questions:

   a. On the one hand, this change conforms the section to encompass all of the new section 4 authorities. On the other hand, does it represent an expansion beyond current TSCA by subjecting consent agreements (which EPA uses sometimes under current TSCA) to citizen's civil actions? [There are competing views on this: a concern about expanding the scope of this section vs. ensuring that the adequacy of testing using any of the available instruments is able to be challenged by any party (consent agreements presumably would not be challenged by industry, as the relevant company will have already consented, but if they are not challengeable by others, that raises a concern).]
   b. Under what circumstances would EPA expect to use a testing consent agreement rather than a test order? How would that decision potentially be affected if it were the case that only the latter action was subject to citizens' civil actions?

Thanks for your assistance; a response at your earliest convenience is requested.

SEC. 13. EXPORTS.

Section 12 of the Toxic Substances Control Act (15 U.S.C. 2611) is amended—

(1) in subsection (a), by striking paragraph (2) and inserting the following:

"(2) EXCEPTION.—Paragraph (1) shall not apply to any chemical substance for which ~~that~~ the Administrator determines the exported portion—

"(A) under section 5, with respect to risks within the U.S., is ~~not~~ likely to present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors~~meet the safety standard within the U.S.~~; or

"(B) under section 6, with respect to risks within the U.S., does ~~not~~ present or will present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors~~meet the safety standard within the U.S.~~.

SEC. 16. PENALTIES.

Section 16 of the Toxic Substances Control Act (15 U.S.C. 2615) is amended—

...

"(2) IMMINENT DANGER OF DEATH OR SERIOUS BODILY INJURY.—

"(A) IN GENERAL.—Any person that knowingly or willfully violates any provision of section 15 or 409~~this Act~~, and that knows at the time of the violation that the violation places an individual in imminent danger of death or serious bodily injury, shall be subject on conviction to a fine of not more than $250,000, or imprisonment for not more than 15 years, or both.

"(B) ORGANIZATIONS.—An organization that commits a violation described in subparagraph (A) shall be subject on conviction to a fine of not more than $1,000,000 for each violation.

"(C3) KNOWLEDGE OF IMMINENT DANGER OR INJURY.—~~For purposes of determining whether a defendant knew that the violation placed another individual in imminent danger of death or serious bodily injury—~~

~~"(A) the defendant shall be responsible only for actual awareness or actual belief possessed; and~~

~~"(B) knowledge possessed by an individual may not be attributed to the defendant.~~ In determining whether a defendant who is an individual knew that the violation placed another person in imminent danger of death or serious bodily injury—

"(i) the defendant is responsible only for actual awareness or actual belief possessed; and

"(ii) knowledge possessed by a person other than the defendant, but not by the defendant, may not be attributed to the defendant;

except that in proving a defendant's possession of actual knowledge, circumstantial evidence may be used, including evidence that the defendant took affirmative steps to be shielded from relevant information.

"(D) AFFIRMATIVE DEFENSE.—It is an affirmative defense to a prosecution that the conduct charged was freely consented to by the person endangered and that the danger and conduct charged were reasonably foreseeable hazards of—

"(i) an occupation, a business, or a profession; or

"(ii) medical treatment or medical or scientific experimentation conducted by professionally approved methods and such other person had been made aware of the risks involved prior to giving consent.

The defendant may establish an affirmative defense under this subparagraph by a preponderance of the evidence.

"(E) DEFENSES.—All general defenses, affirmative defenses, and bars to prosecution that may apply with respect to other Federal criminal offenses may apply under subparagraph (A) of this paragraph and shall be determined by the courts of the

United States according to the principles of common law as they may be interpreted in the light of reason and experience. Concepts of justification and excuse applicable under this section may be developed in the light of reason and experience.

"(F) DEFINITIONS.—

"(i) The term "organization" means a legal entity, other than a government, established or organized for any purpose, and such term includes a corporation, company, association, firm, partnership, joint stock company, foundation, institution, trust, society, union, or any other association of persons.

"(ii) The term "serious bodily injury" means bodily injury which involves a substantial risk of death, unconsciousness, extreme physical pain, protracted and obvious disfigurement or protracted loss or impairment of the function of a bodily member, organ, or mental faculty.".

SEC. 19. CITIZENS' CIVIL ACTIONS.

Section 20 of the Toxic Substances Control Act (15 U.S.C. 2619) is amended—

(1) in subsection (a)(1) by striking "or order issued under section 5" and inserting "consent agreement or order issued under section 4, or order issued under section 5"; and

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/16/2015 5:18:05 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
CC: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
Subject: RE: Additional TA requests | Exports - Penalties - Citizen's Civil Actions

Yes, response coming shortly.

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Tuesday, June 16, 2015 1:18 PM
To: Kaiser, Sven-Erik
Cc: Karakitsos, Dimitri (EPW)
Subject: RE: Additional TA requests | Exports - Penalties - Citizen's Civil Actions

Thanks. Any updates on these?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, June 11, 2015 1:54 PM
To: Black, Jonathan (Tom Udall)
Cc: Karakitsos, Dimitri (EPW)
Subject: RE: Additional TA requests | Exports - Penalties - Citizen's Civil Actions

Got it - circulating

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Thursday, June 11, 2015 1:53 PM
To: Kaiser, Sven-Erik
Cc: Karakitsos, Dimitri (EPW); Black, Jonathan (Tom Udall)
Subject: Additional TA requests | Exports - Penalties - Citizen's Civil Actions
Importance: High

Sven, we have been diligently working through your TA:

I think we've made a lot of progress, but now there are three areas we still need some attention.

1. Section 13, Exports (see attachment): The change you suggested earlier has been inserted into paragraphs (2)(A) and (B).

Question: Is further clarification needed as to whether those determinations are:

a. limited to risks in the U.S., and
b. limited to the manufacture, processing, and distribution in commerce of the exported portion of the chemical substance?

Possible text additions to address each of these are shown on lines 4-5 and 6 and 7.

2. Section 16, Penalties (see attachment): Per your earlier TA, we have incorporated verbatim language from the Clean Air Act section 113(c)(5)(B) regarding "knowledge of imminent danger or injury," "affirmative defenses," and "defenses," as well as relevant definitions. **This represents a lot of new text, however.**

   Question: Is there a way to incorporate all of this by reference?

3. Section 19, Citizen's Civil Actions (see attachment): Per your earlier TA, we have expanded the section 4 actions subject to this section to include testing consent agreements and test orders, as well as test rules.

   Questions:

   a. On the one hand, this change conforms the section to encompass all of the new section 4 authorities. On the other hand, does it represent an expansion beyond current TSCA by subjecting consent agreements (which EPA uses sometimes under current TSCA) to citizen's civil actions? [There are competing views on this: a concern about expanding the scope of this section vs. ensuring that the adequacy of testing using any of the available instruments is able to be challenged by any party (consent agreements presumably would not be challenged by industry, as the relevant company will have already consented, but if they are not challengeable by others, that raises a concern).]
   b. Under what circumstances would EPA expect to use a testing consent agreement rather than a test order? How would that decision potentially be affected if it were the case that only the latter action was subject to citizens' civil actions?

Thanks for your assistance; a response at your earliest convenience is requested.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/17/2015 8:57:32 PM
To: Zipkin, Adam (Booker) [Adam_Zipkin@booker.senate.gov]
Subject: Sen. Booker TSCA TA Request on compound 1080

Adam,
Checking. Thanks,
Sven

On Jul 17, 2015, at 4:07 PM, "Zipkin, Adam (Booker)" <Adam_Zipkin@booker.senate.gov> wrote:

Hello Sven. Within my office the idea is being discussed of a possible amendment to Section 6 of TSCA to prohibit the use, production, sale, importation, or exportation of sodium fluoroacetate (known as 'Compound 1080'). At this point I have not proposed adding this to the bill sponsors, and wanted to see if EPA had any TA and/or history with Compound 1080 that you could share? Thanks. Adam

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/16/2015 5:46:01 PM
To: 'Zipkin, Adam (Booker)' [Adam_Zipkin@booker.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Senate TSCA TA on Small Manufacturers Definition

Adam,
This responds to the technical assistance request on the draft language on small manufacturers. It may be infeasible to complete the full process specified in 8(a)(3)(C) within 180 days. The specified process appears to include: (1) completing an economic analysis, after consultation with the SBA; (2) publishing a proposed determination based on that analysis, reviewing public comments, and publishing a final determination; and (3) as warranted, completing a full rulemaking process to revise the standards for qualifying as a "small manufacturer or processor." A more realistic allotment of time would be 18 months.

Note also that the standards made subject to re-analysis here are only applicable to 8(a)(1) (which establishes a default prohibition on requiring reporting from small manufacturers and processors) and 8(a)(3) (which establishes a limited exception to the default prohibition at 8(a)(1)). Yet the bill introduces parallel reporting authorities under paragraph (4). The 8(a)(4) authority is largely coextensive with the 8(a)(1) authority, but operates under a separate standard for addressing burden to small manufacturers and processors ("minimize the impact . .. on small manufacturers and processors").

The technical assistance is intended for use only by the requesters. The technical assistance does not necessarily repr3esent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
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202-566-2753

SEC. 10. INFORMATION COLLECTION AND REPORTING.

Section 8 of the Toxic Substances Control Act (15 U.S.C. 2607) is amended—

(1) in subsection (a)—

(A) in paragraph (3)(A)(ii)(I)—

(i) by striking "5(b)(4)" and inserting "5";

(ii) by inserting "section 4 or" after "in effect under"; and

(iii) by striking "5(e)," and inserting "5(d)(4);"; and

(B) in paragraph (3), by adding at the end the following:

"(C) Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and not less frequently than once every 10 years thereafter, the Administrator shall, after consultation with the Administrator of the Small Business Administration, review the adequacy of the standards prescribed according to subparagraph (B) and, after providing

public notice and an opportunity for comment, make a determination as to whether revision of the standards is warranted, and revise the standards if the Administrator so determines.";

Current TSCA section 8(a)(3):
(3)
(A)
(i) The Administrator may by rule require a small manufacturer or processor of a chemical substance to submit to the Administrator such information respecting the chemical substance as the Administrator may require for publication of the first list of chemical substances required by subsection (b) of this section.
(ii) The Administrator may by rule require a small manufacturer or processor of a chemical substance or mixture—
(I) subject to a rule proposed or promulgated under section 2603, 2604 (b)(4), or 2605 of this title, or an order in effect under section 2604 (e) of this title, or
(II) with respect to which relief has been granted pursuant to a civil action brought under section 2604 or 2606 of this title,
to maintain such records on such substance or mixture, and to submit to the Administrator such reports on such substance or mixture, as the Administrator may reasonably require. A rule under this clause requiring reporting may require reporting with respect to the matters referred to in paragraph (2).
(B) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the manufacturers and processors which qualify as small manufacturers and processors for purposes of this paragraph and paragraph (1).

From: Zipkin, Adam (Booker) [mailto:Adam_Zipkin@booker.senate.gov]
Sent: Tuesday, July 14, 2015 8:35 PM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW); Deveny, Adrian (Merkley)
Subject: RE: Senate TSCA TA on Small Manufacturers Definition

Sven on this issue of definition of small manufacturer, please see red-line language on page 35 of attached document – please advise if EPA has any TA. Thanks. Adam

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/16/2015 4:03:09 PM
To: 'Couri, Jerry' [JerryCouri@mail.house.gov]
Subject: HEC TSCA FACA question
Attachments: CSAC_Charter.pdf

Jerry,
Responding to your question, on Friday, June 12, 2015, EPA announced the establishment of the Chemical Safety Advisory Committee (CSAC) and solicited nominations for membership on the Committee. The purpose of the CSAC, which is established under the Federal Advisory Committee Act, is to provide expert scientific advice, information, and recommendations to EPA's Office of Pollution Prevention and Toxics on the scientific basis for risk assessments, methodologies, and pollution prevention measures or approaches. The Federal Register notice announcing establishment of the CSAC can be found at http://www.gpo.gov/fdsys/pkg/FR-2015-06-12/pdf/2015-14331.pdf

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Couri, Jerry [mailto:JerryCouri@mail.house.gov]
Sent: Wednesday, July 15, 2015 9:51 AM
To: Kaiser, Sven-Erik
Subject: FACA question

Good Morning.

I understand EPA recently announced it is creating a new advisory committee, called the Chemical Safety Advisory Committee. I'm trying to find this new committee's charter. Do you know where I can find it?

Thanks.

Gerald S. Couri
Senior Environmental Policy Advisor | Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Building | 202.226.9603 (direct)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/15/2015 3:18:30 PM
To: 'Cohen, Jacqueline' [jackie.cohen@mail.house.gov]
Subject: HEC Inquiry on Aluminum and Partial Reporting Exemptions

Jacqueline,
This responds to your inquiry about aluminum and the partial exemption process.

The aluminum petitions were submitted under a partial exemption petition process that is established by rule, as a part of the CDR. (At the time the petitions were submitted, the petition process was set forth at 40 CFR 710.46(b)(2). The reporting rule was later re-codified, and the regulations defining this petition process were moved at 40 CFR 711.6(b)(2)).

Assuming you are specifically inquiring about exemptions from reporting under TSCA Section 8(a), in addition to the provisions you noted, there are other aspects of Section 8(a) that affect the scope of reporting:

- Section 8(a) reporting requirements can only apply to manufacturers or processors. For purposes of TSCA Section 8, manufacturing and processing only refers to manufacturing or processing "for commercial purposes." See TSCA 8(f). Other kinds of manufacturing and processing are thus outside the scope of TSCA Section 8 reporting.
- TSCA Section 8(a) specifies that reporting requirements for the manufacturing and processing of chemical substances must be reasonable requirements.
- Reporting requirements for the manufacturing and processing of mixtures, or the manufacturing and processing of chemical substances in small quantities for R&D purposes, must be justified based on heightened standards.

Based on the authority of Section 8(a), the CDR sets forth reporting exemptions in more detail.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Cohen, Jacqueline [mailto:jackie.cohen@mail.house.gov]
Sent: Tuesday, July 14, 2015 4:41 PM
To: Kaiser, Sven-Erik
Subject: a couple follow up questions on aluminum

Was the aluminum petition filed under a formal petition provision? Is there anything in the statute that anticipates exemptions from reporting, other than small business exemptions and limitations for duplicative reporting?

Jacqueline G. Cohen
Senior Counsel
Committee on Energy and Commerce, Democratic Staff
U.S. House of Representatives
jacqueline.cohen@mail.house.gov
202-225-4407

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/15/2015 1:23:15 PM
To: 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]; 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: RE: Senate TSCA TA Request on Nomenclature

The schedule is narrower than I thought – availability this morning until noon, 3-4, and after 5. Thanks, Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Kaiser, Sven-Erik
Sent: Wednesday, July 15, 2015 9:19 AM
To: 'Karakitsos, Dimitri (EPW)'
Cc: Black, Jonathan (Tom Udall)
Subject: Senate TSCA TA Request on Nomenclature

Dimitri,
This responds to your technical assistance request on nomenclature language. Please take a look at the TA below and let me know if you would like a call today to discuss. We're open today except 12-1 and 4-5.
Thanks,
Sven

The apparent intent of the new language is for EPA to establish a procedure whereby manufacturers of new "Class 2 substances from new renewable sources" can obtain exemptions from otherwise applicable PMN requirements, if "sufficiently similar" chemical substances are already listed on the TSCA Inventory. The way to achieve this objective without triggering serious implementation concerns is by defining a new basis for exemption from Section 5, and then directing EPA to further elaborate the exemption process by rule.

The current drafting is problematic in two key respects:

- First, because it is structured as a "nomenclature" issue, the language does not specify who is responsible for doing what. For example, what does it mean for one chemical substance to "rely" on another chemical substance? This cannot be construed literally. Is the intended implication that the prospective manufacturer of one chemical substance may unilaterally "rely" on the fact that another chemical substance is listed on the Inventory, and thus conclude that it has no duty to submit a PMN? Or does the prospective manufacturer have a duty to submit an application to EPA and persuade EPA that the two chemical substances are indeed sufficiently similar and that the renewable source in question is sufficiently "new"?

- Second, by framing this provision as a general "nomenclature" issue, it suggests a broader principle: that when EPA adds a chemical substance to the TSCA Inventory, the listing represents not just that one substance but also all "sufficiently similar" chemicals. This is not how EPA currently implements the TSCA Inventory, and redefining the operation of Inventory could have far-reaching and unintended consequences (e.g., when reviewing a new chemical substance, would EPA need to make the "likely to meet the safety standard" finding not only for that one chemical but also for all "sufficiently similar" chemicals?). The general premise of the TSCA Inventory, to date, has been that two different chemical

substances require two different entries on the TSCA Inventory, even if they are similar chemical substances. Departing from this basic premise is likely to make the naming and listing process more complex and less transparent.

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and comments.

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
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Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Tuesday, July 14, 2015 2:54 PM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall)
Subject: TA Question

Sven,

Quick question for you, any TA we could get back as soon as possible on this would be much appreciated. I think your folks will understand the purpose but it has been proposed to me that we add this language in red below. Want to make sure it would work and not be impossible to implement or objectionable.

Thanks!

((3) NOMENCLATURE.—
(A) IN GENERAL.—In carrying out paragraph
(1), the Administrator shall—
(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); ~~**and**~~

(iii) establish a process in which Class 2 substances from new renewable sources are evaluated against existing Class 2 substances for equivalence; if an existing Class 2 substance can be found that is sufficiently similar to the new Class 2 substance derived from a renewable source, the new Class 2 substance can rely on the Inventory listing of the existing Class 2 substance; and

(iv) treat all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation—
(I) cement, Portland, chemicals,CAS No. 65997–15–1;
(II) cement, alumina, chemicals, CAS No. 65997–16–2;
(III) glass, oxide, chemicals, CAS No. 65997–17–3;
(IV) frits, chemicals, CAS No. 6 65997–18–4;
(V) steel manufacture, chemicals, CAS No. 65997–19–5; and

(VI) ceramic materials and wares, chemicals, CAS No. 66402–11 68–4.

Dimitri J. Karakitsos
Majority Senior Counsel
Senate Committee on
Environment and Public Works
(202) 224-6176

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/15/2015 1:17:29 AM
To: Zipkin, Adam (Booker) [Adam_Zipkin@booker.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Re: Senate TSCA TA on Small Manufacturers Definition

Got it,
Thanks

On Jul 14, 2015, at 8:35 PM, "Zipkin, Adam (Booker)" <Adam_Zipkin@booker.senate.gov> wrote:

Sven on this issue of definition of small manufacturer, please see red-line language on page 35 of attached document – please advise if EPA has any TA. Thanks. Adam

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, July 10, 2015 2:34 PM
To: Zipkin, Adam (Booker); Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW); Deveny, Adrian (Merkley)
Subject: Senate TSCA TA on Small Manufacturers Definition

Adam,
This responds to the TA request on defining small manufacturers. To be clear, no, EPA wasn't considering updating the definition of small manufacturer in the CDR rulemaking.

The primary reason why the small manufacturer definition is meaningful is because it affects who must report under CDR. That's why our last TA noted how we had considered potential small business impacts of the CDR using both the TSCA and the SBA definitions. The SBA participated in the interagency review process for that rulemaking.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Zipkin, Adam (Booker) [mailto:Adam_Zipkin@booker.senate.gov]
Sent: Friday, July 10, 2015 9:33 AM
To: Kaiser, Sven-Erik; Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW); Deveny, Adrian (Merkley)
Subject: RE: SEPW TSCA TA

Sven so that I am clear – on #3 regarding small manufacturers, are you saying that in 2011 EPA considered updating/revising the 1984 definition and decided that no change was warranted? Was SBA consulted?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, July 02, 2015 9:29 AM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW); Zipkin, Adam (Booker); Deveny, Adrian (Merkley)
Subject: SEPW TSCA TA

Jonathan,
This technical assistance responds to several requests. The language on small manufacturers is in addition to earlier TA on the same subject. The technical assistance is intended for use only by the requesters. The technical assistance does not necessarily repr3esent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

1. Regarding the "denominator issue":

The following suggested redrafting is intended to effectuate what we understand to be the policy objective behind section 4A(c)(2)(A) without suggesting, as the current draft does, that "additional priorities" designated under 4A(c)(1) are a subset of high priority chemicals designated under subsections 4A(a)(2) or (b)(3). Our understanding of the policy objective is that, in calculating the number of additional priority chemicals, the denominator for the required 25%-30% range should be the number of high-priority chemicals designated under those subsections, not the total number of chemicals designated to undergo safety assessments and safety determinations. Redline is from the version voted out of Committee:

Sec 4A(c)(2)(A) – if a sufficient number of additional priority requests meet the requirements of paragraph (1), the number of substances designated to undergo safety assessments and safety determinations under the process and criteria pursuant to paragraph (1) shall be not less than 25 percent, or more than 30 percent, of the cumulative number of substances designated to undergo safety assessments and determinations under subsections (a)(2) and (b)(3). this section are substances designated under the process and criteria pursuant to paragraph (1).

2. Regarding imports:

- Following is the new text that you requested, addressing existing chemical substances that were added to the TSCA inventory, after a Section 5 determination that they were not likely to meet the safety standard. Such a determination would trigger restriction under 5(d)(4), which would be part of the basis for a new exception to the export exemption.

- This resolves the technical concern about an exported new chemical substance being made subject to TSCA under (A) and then ceasing to be subject to TSCA as soon as the chemical substance becomes an existing chemical subject to a section 5 order. Once the chemical is added to the Inventory, it would remain excepted from the export exemption, but now under (C) rather than under (A).

- This also provides that if domestic uses of a new chemical substance are restricted under a section 5 order, it would only take a "likely to present" finding, with respect to the exported volumes, to later make the exported volumes of such chemical substance subject to TSCA jurisdiction.

"(2) EXCEPTION.—Paragraph (1) shall not apply to—

"(A) any new chemical substance that the Administrator determines is likely to present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors; or
"(B) any chemical substance that the Administrator determines presents or will present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors; or
"(C) any chemical substance that:

(i) the Administrator determines is likely to present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors; and

(ii) is subject to restriction under section 5(d)(4)

3. Regarding small manufacturers:

- For purposes of Chemical Data Reporting, the operative definition of "small manufacturer or importer" is found at 40 CFR 704.3. Chemical manufacturers that fall under this definition are generally exempt from reporting. 40 CFR 711.9. The standard used in the definition of "small manufacturer or importer" was established in 1984. 49 FR 45425. In 2011, EPA analyzed potential small business impacts of Chemical Data Reporting using both the SBA employee size standards and the TSCA sales-based definition of small business. 76 FR 50858.

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, June 29, 2015 2:06 PM
To: Kaiser, Sven-Erik; Karakitsos, Dimitri (EPW); Zipkin, Adam (Booker); Deveny, Adrian (Merkley)
Subject: RE: SEPW TSCA TA

Thanks! I'm glad someone is keeping track!

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, June 29, 2015 2:05 PM

To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW); Zipkin, Adam (Booker); Deveny, Adrian (Merkley)
Subject: SEPW TSCA TA

Jonathan,
I think there are 3 outstanding TA requests below. The first two are underway and included is the response to the small manufacturers definition question. Please let me know if any additional questions.
Thanks,
Sven

- exports (EPA working on TA)

- cap on industry assessments (EPA to provide text change on p.22, line 18)

- small manufacturers definition

EPA response: most of EPA's TSCA programs, including CDR, use the same definition for small business as defined by regulation in 40 CFR 704.3. This definition has never been updated. A few TSCA programs use different definitions of small business, including for 8(a) PAIR and for calculating PMN fees.

Small manufacturer or importer means a manufacturer or importer that meets either of the following standards:

(1) First standard. A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $40 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer or importer is greater than 45,400 kilograms (100,000 pounds), the manufacturer or importer shall not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer or importer qualifies as small under standard (2) of this definition.

(2) Second standard. A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $4 million, regardless of the quantity of substances produced or imported by that manufacturer or importer.

(3) Inflation index. EPA shall make use of the Producer Price Index for Chemicals and Allied Products, as compiled by the U.S. Bureau of Labor Statistics, for purposes of determining the need to adjust the total annual sales values and for determining new sales values when adjustments are made. EPA may adjust the total annual sales values whenever the Agency deems it necessary to do so, provided that the Producer Price Index for Chemicals and Allied Products has changed more than 20 percent since either the most recent previous change in sales values or the date of promulgation of this rule, whichever is later. EPA shall provide Federal Register notification when changing the total annual sales values.

Sven-Erik Kaiser
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Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, June 29, 2015 1:37 PM
To: Kaiser, Sven-Erik
Cc: Karakitsos, Dimitri (EPW); Zipkin, Adam (Booker); Deveny, Adrian (Merkley)
Subject: Follow-up

Hey Sven, sorry again to miss the call last week. My understanding was there might be one more follow-up on exports? Are we waiting for anything from EPA?

<EPA TA - Orion - (7-10-15) - redline w explanation comments - v 2 1 with p 35 redline.rtf>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/14/2015 6:54:12 PM
To: 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: RE: TA Question

Got it - checking

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Tuesday, July 14, 2015 2:54 PM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall)
Subject: TA Question

Sven,

Quick question for you, any TA we could get back as soon as possible on this would be much appreciated. I think your folks will understand the purpose but it has been proposed to me that we add this language in red below. Want to make sure it would work and not be impossible to implement or objectionable.

Thanks!

((3) NOMENCLATURE.—
(A) IN GENERAL.—In carrying out paragraph
(1), the Administrator shall—
(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); ~~and~~

(iii) establish a process in which Class 2 substances from new renewable sources are evaluated against existing Class 2 substances for equivalence; if an existing Class 2 substance can be found that is sufficiently similar to the new Class 2 substance derived from a renewable source, the new Class 2 substance can rely on the Inventory listing of the existing Class 2 substance; and

(iv) treat all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation—
(I) cement, Portland, chemicals,CAS No. 65997–15–1;
(II) cement, alumina, chemicals, CAS No. 65997–16–2;

(III) glass, oxide, chemicals, CAS No. 65997–17–3;
(IV) frits, chemicals, CAS No. 6 65997–18–4;
(V) steel manufacture, chemicals, CAS No. 65997–19–5; and
(VI) ceramic materials and wares, chemicals, CAS No. 66402–11 68–4.

Dimitri J. Karakitsos
Majority Senior Counsel
Senate Committee on
Environment and Public Works
(202) 224-6176

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 1/7/2016 4:37:56 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA Followup Request on Unreasonable Risk

Michal,
This responds to the followup TA request on unreasonable risk. Please let me know if any additional questions.
Thanks,
Sven

EPA Response:

We noted earlier that if the 4(a)(1)(A)(i) finding were changed to require only a showing that EPA has "a basis for concern," we believe that language – plus the fact that Congress intentionally moved away from the "may present" standard – would give EPA a good basis to require testing of such a chemical in the absence of information demonstrating that the chemical posed little or no hazard.

Your question relates to the likely effect of a hybrid standard: "basis for concern . . . [that certain activities involving a chemical substance] may present an unreasonable risk." We think a court would very likely construe such a change from current TSCA as lessening the requirements on EPA to justify testing, relative to the current "may present an unreasonable risk" standard.

According to a leading case interpreting current 4(a)(1)(A)(i), the following is currently required: "a more-than-theoretical basis for concluding that the substance is sufficiently toxic, and human exposure to it is sufficient in amount, to generate an unreasonable risk of injury to health." CMA v. U.S. EPA, 859 F.2d 977 (D.C. Cir. 1988) (internal quotes omitted). Under the standard you are suggesting here, it is likely that something less searching would be required, yet still more searching than merely showing that the chemical hazard is non-negligible (i.e., more than that EPA merely has some "basis for concern"). Interpolating between these two points of reference, we believe it would be reasonable to interpret the intermediate standard as:

<< a more-than-theoretical basis for **concern** that the substance **could be** sufficiently toxic, and human exposure **could be** sufficient in amount, to generate an unreasonable risk of injury to health.>>

This would not likely require actual or documented hazard information. Information respecting potential hazard and a potential route of exposure would likely suffice.

Irrespective of the 4(a)(1)(A)(i) standard, EPA would still need to show that there are insufficient data and experience as to the chemical to enable the Agency to determine or predict the effects of the chemical, and that testing is necessary to close the data gaps. This is under 4(a)(1)(A)(ii) and (iii).

Sven-Erik Kaiser
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202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, December 23, 2015 12:52 PM

To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Request on Unreasonable Risk - SECTION 4 AND SECTION 6

Sven – just checking in to see whether this formulation works to address the catch-22? And if not, can you suggest a better formulation? No worries if relevant staff are out of the office, early in the new year is fine for response.

SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.

(a) TESTING REQUIREMENTS.—If the Administrator finds that—

(1)(A)(i) there is a basis for concern that the manufacture, distribution in commerce, pro-cessing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, December 16, 2015 5:35 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on Unreasonable Risk - SECTION 4 AND SECTION 6

Michal,
This responds to your technical assistance request on "unreasonable risk." Please let me know if any questions. Thanks,
Sven

Question: If the section 4 test finding catch 22 was removed or changed to something like "basis for concern" or something like that, under House text, would EPA be able to request some data from industry on a chemical that was ubiquitous but about which little was known in order to establish some potential for hazard (and then be able to proceed with a risk evaluation)? I don't think I read the House bill as allowing this, I think I read it as allowing testing once a risk evaluation is already underway. But if so, would EPA be likely to use its section 4 authority and resources that way, or would it be more likely to use it on substances for which the "may pose an unreasonable risk" section 6 finding could more easily be made?

EPA Response: TSCA section 4 provides two bases for requiring testing: a finding the a chemical substance may present unreasonable risk (4(a)(1)(A)), and a finding based on production volume, release and/or exposure (4(a)(1)(B)). You previously asked whether the section 4 findings could be made for ubiquitous chemicals, and our answer was that they likely could under (B), but only for chemicals manufactured at substantial volumes. We understand that you now want to know if a change to the (A) findings would provide another, perhaps more certain, basis to require testing for ubiquitous chemicals.

We think it would, if by "ubiquitous" you mean a chemical with widespread exposure. If the (A) finding were changed to require only a showing that EPA has a basis for concern, we believe that language – plus the fact that Congress intentionally moved away from the "may present" standard – would give EPA a good basis to require testing of such a chemical in the absence of information demonstrating that the chemical posed little or

no hazard. EPA would still need to show that there are insufficient data and experience as to the chemical to enable the Agency to determine or predict the effects of the chemical, and that testing is necessary to close the data gaps – findings that EPA must make under both (A) and (B) (4(a)(1)(A)(ii) and (iii), 4(a)(1)(B)(ii) and (iii)). But, again, for a chemical with widespread exposure, we think EPA would most likely be able to demonstrate a basis for concern so long as the Agency could show that there were open questions about hazard.

You also suggest the possibility of simply dropping the "may present" standard, rather than replacing it. We don't think that would make sense, since the (A) basis for testing would have no function if it contained no standard.

Finally, you asked whether or not EPA would be likely to use section 4, if given the authority, to help clear the hurdle to initiating a risk evaluation under section 6 of the House bill. We would not want to rule out this use of section 4 authority, but think such use would be fairly minimal, particularly in the earlier years of implementation when the focus would be on TSCA Work Plan chemicals and other chemicals that for which there is some information. EPA would interpret the bar for initiating a risk evaluation on non-Work Plan chemicals under 6(b)(3)(A)(i) as fairly low. The House language requires that EPA make a finding that the chemical substance "may present an unreasonable risk," but that finding is based on potential hazard and a potential route of exposure. We interpret this as not requiring actual or documented hazard/exposure information. And because we don't anticipate the 6(b)(3)(A)(i) finding to be a significant barrier to initiating risk evaluations, we also don't anticipate a regular need to invoke section 4 testing authority to overcome it. A more likely use of section 4 would be to support necessary analysis during the risk evaluation, and ultimately, a determination of whether or not the chemical substance "presents or will present…an unreasonable risk."

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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Sunday, December 06, 2015 9:53 AM
To: Distefano, Nichole <DiStefano.Nichole@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Subject: TA request (for starting on Monday)

Nichole

We've very much appreciated the rapid turn around on questions related to the "may pose an unreasonable risk" section 4 and 6 text of House/TSCA, as well as efforts to understand what it could mean for EPA to have to determine both potential exposure and potential hazard under section 6 before starting a risk evaluation.

I'm trying to understand whether the solution on section 6 could be in section 4.

If the section 4 test finding catch 22 was removed or changed to something like "basis for concern" or something like that, under House text, would EPA be able to request some data from industry on a chemical that was ubiquitous but about which little was known in order to establish some potential for hazard (and then be able to proceed with a risk evaluation)? I don't think I read the House bill as allowing this, I think I read it as allowing testing once a risk evaluation is already underway. But if so, would EPA be likely to use its section

4 authority and resources that way, or would it be more likely to use it on substances for which the "may pose an unreasonable risk" section 6 finding could more easily be made?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/10/2015 9:56:03 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]; Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]; Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Hunt, Jasmine (Durbin) [Jasmine_Hunt@durbin.senate.gov]; Zimmerman, Melissa (Appropriations) [Melissa_Zimmerman@appro.senate.gov]
Subject: Senate TSCA TA on Appropriations and Fees
Attachments: Senate TSCA TA on Fees and Appropriations.docx

Jonathan,
The attached technical assistance responds to your request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions.
Thanks,
Sven

Sven-Erik Kaiser
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Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Friday, July 10, 2015 2:09 PM
To: Kaiser, Sven-Erik
Cc: Freedhoff, Michal (Markey); Karakitsos, Dimitri (EPW); Hunt, Jasmine (Durbin); Zimmerman, Melissa (Appropriations)
Subject: Minimum appropriations

Sven, can you run this construct by your folks to ensure that this is appropriately drafted? Based on our conversations with you yesterday.

> "(D) MINIMUM AMOUNT OF APPROPRIATIONS.—Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for salaries, contracts, and expenses for the functions (as in existence in fiscal year 2014) of the ~~Office of Pollution Prevention and Toxics of the Environmental Protection Agency for~~ Chemical Risk Review and Reduction activity of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for covered functions for fiscal year 2014 (excluding the amount of any fees appropriated for the fiscal year).

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

"(D) MINIMUM AMOUNT OF APPROPRIATIONS.—Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for ~~the salaries, contracts, and expenses for the functions (as in existence in fiscal year 2014) of the Office of Pollution Prevention and Toxics of the Environmental Protection Agency for~~ Chemical Risk Review and Reduction ~~program project activity~~ of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for ~~that program project covered functions~~ for fiscal year ~~2014 (excluding the amount of any fees appropriated for the fiscal year)~~.

Commented [A1]: The intent of the parallel language in FIFRA/PRIA is to ensure that the year-to-year appropriation comparison is tied to a snapshot of the activities that were already ongoing in the Office of Pesticide Programs at the time the appropriations baseline was established. That is, to maintain funding by comparison to functions already ongoing.

Yet this bill may significantly alter the functions that will be occurring under this program project. The presumed intent here is to use the 2014 program project as the measuring stick, without assuming that the functions occurring under the program project will be unaltered by the bill. The edits are to accomplish the drafters' presumed intent.

Without changes along the lines suggested here there is a risk that EPA might not be able to "count" certain appropriations within the program project (i.e., towards satisfying the funding requirements for fees) if they do not match up with functions that already existed in 2014.

Commented [A2]: Activity is a subset of a program project. What you have just named is a program project, not an activity.

Commented [A3]: This change (reflected in the incoming document) makes the bill clearer, since the language, as revised, matches a program project from EPA's budget. Since the actual text of Congressional appropriations would likely not specify particular programs, EPA would still need to interpret the appropriation (e.g., in light of the Committee Report accompanying the appropriation) to determine whether the Agency was still authorized to assess fees under TSCA. But this change will make the interpretation process easier.

Commented [A4]: "Covered functions" is not defined in the bill, as it is in FIFRA/PRIA.

See also above discussion of the problem with locking the funding baseline to functions already ongoing in 2014.

Commented [A5]: Was it intentional to change the fees baseline from 2015 to 2014?

Commented [A6]: This doesn't make any sense when moved from the FIFRA context to the TSCA context. There are no 2014 appropriations for EPA to spend fees collected under TSCA.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 1/5/2016 9:25:38 PM
To: 'Fruci, Jean' [Jean.Fruci@mail.house.gov]; Kessler, Rick [Rick.Kessler@mail.house.gov]; Wright, Tuley [Tuley.Wright@mail.house.gov]
Subject: HEC min TSCA TA Request on Savings Clause
Attachments: HEC Min.TSCA TA.Savings Clauses.docx; HEC min.TSCA TA.18(c)(1) Savings Clause.docx

Jean – attached is TA on savings clauses along with TA on the scope of preemption. Also attached is the earlier TA provided on the section 18(c)(1) savings clause. Please let us know if you still want TA on nomenclature and if there is language to consider. Lastly, are you still interested in discussing the implications changing "unreasonable risk?" Perhaps a call would be helpful. Please let me know if any additional questions.
Best,
Sven

Sven-Erik Kaiser
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Washington, DC 20460
202-566-2753

From: Fruci, Jean [mailto:Jean.Fruci@mail.house.gov]
Sent: Wednesday, December 16, 2015 7:33 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Kessler, Rick <Rick.Kessler@mail.house.gov>; Wright, Tuley <Tuley.Wright@mail.house.gov>
Subject: request for technical assistance

Sven:

Thanks for arranging today's call on TSCA. As a follow-up to today's discussion, we would like to have some assistance with the following:

1) Alternative language to clarify the savings clauses to preserve existing state authorities under TSCA – especially with respect to Proposition 65.
2) Alternative language to clarify the scope of pre-emption such that states' ability to act on chemical uses or health endpoints that EPA did not consider in a risk evaluation/risk management of a chemical is preserved.
3) Alternative language on "Nomenclature" that preserves the Administrator's discretion to deviate from the conventions listed when necessary to carry out the purposes of the Act. (I have some language for you to consider also). It should be ready sometime tomorrow.
4) Further consideration of the implications of changing "unreasonable risk" in other Sections of TSCA.

I think that does it for now.

Jean

Jean Fruci, Ph.D.
Professional Staff
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

202 225-4407
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''(c) SAVINGS.—

''(1) PRIOR STATE ACTIONS.—Nothing in this title, nor any risk evaluation, rule, order, standard,or requirement completed or implemented under this title, shall be construed to preempt or otherwise affect any action or requirement ~~the authority~~ of a State or political subdivision of a State ~~to continue to enforce any action taken or requirement that has taken effect~~—

''(A) that has been taken or has taken effect before August 1, 2015, under the authority of a State law that prohibits or otherwise restricts the manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance; or

''(B) taken or that takes effect, whether before or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, pursuant to a State law that was in effect on August 31, 2003, unless a requirement imposed ~~a action or determination made~~ by the Administrator under this title actually conflicts with the action or requirement of such State or political subdivision of a State~~that has taken effect pursuant to such a State law~~.

Commented [A1]: This change is to ensure that citizens can enforce un-preempted state requirements, as well as states.

Commented [A2]: The foregoing changes are to make clear that even post-FRL actions are not preempted, so long as they are taken pursuant to state laws in effect before Sept 1, 2003.

Commented [A3]: This change is to narrow the range of interpretations of when a state action "actually conflicts" with EPA action, to the situation where there is actual conflict with Federal *requirements*, as opposed to a difference of opinion as to whether something should be regulated.

Commented [A4]: This change is to avoid the past tense phrasing, which is appropriate for (A) savings but potentially confusing for (B).

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

1. Alternative language to clarify the savings clauses to preserve existing state authorities under TSCA -- especially with respect to Proposition 65.

EPA Response: We sent alternative language earlier for section 18(c)(1). Here is TA on some additional provisions. We interpret "savings clauses" in your question broadly to encompass provisions intended to preserve state law from preemption, whether or not they are designated savings clauses in the bill.

-- Sections 18(a)(2)(B)(i) and 18(a)(2)(C)(ii) preserve a state law if it is "adopted under the authority of a Federal law." This formulation, adopted from TSCA section 18, read literally does not effectuate the broader intent, as reflected in the legislative history of TSCA, to include in the savings clause those requirements that are not actually adopted under Federal authority but rather are adopted under state authority as part of a cooperative federalism scheme under federal law, or that are exempt from preemption under other federal laws. Because EPA has done little substantive regulation under TSCA, there has been little occasion for courts to interpret this provision, and its application is uncertain. The Senate bill contains a more complete formulation: "is adopted or authorized under the authority of any other Federal law or adopted to satisfy or obtain authorization or approval under any other Federal law."

-- Section 18(a)(2)(B)(ii) and 18(a)(2)(C)(iii) preserve a state air, water or waste requirement unless a provision of TSCA "or an action or determination made by the Administrator under this title, actually conflicts with the requirement". As we pointed out in our TA on section 18(c)(1), it is not clear what would constitute an actual conflict with an EPA "determination". For example, if EPA decides not to regulate an air impact under TSCA, is a state then preempted from regulating such an impact under a state air law? Or is the intention to preempt only state requirements that are in conflict with federal requirements? If the latter is intended, that could be clarified by striking "an action or determination made" and substituting "a requirement imposed" in both provisions.

-- Section 18(c)(3) provides that the revised TSCA and EPA actions under it are not intended to influence the disposition of state civil damages actions or state court evidentiary determinations. There does not appear to be any other provision of this bill that purports to limit, in certain circumstances, the prerogatives of a state court to rule on the admissibility of evidence or determine the prevailing party in a civil suit, so it is unclear what sort of preemptive effect is being maintained by this caveat. Also, it is not clear how any "provision of this title" could "actually conflict[]" with a decision of a state judge in particular case.

-- Section 18(c)(2) broadly saves from preemption states laws governing torts (under "any. . . legal theory relating to tort law") and the interpretation of contracts, but section 18(c)(4) provides that the term "requirements" in the bill does not include "civil tort actions for damages under State law." Thus, the latter provision appears to reflect a narrower savings than the former. It is not clear to us what section 18(c)(4) adds to the bill, so a possible solution would be to drop it. An alternative approach would be to drop 18(c)(4) but add at the end of 18(c)(2): "For purposes of this title, the term 'requirements' does not include any such Federal or State law."

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

2) Alternative language to clarify the scope of pre-emption such that states' ability to act on chemical uses or health endpoints that EPA did not consider in a risk evaluation/risk management of a chemical is preserved.

EPA Response:

'(B) if the Administrator makes a final determination under section 6(b) that a chemical substance will not present an unreasonable risk of injury to health or the environment under the intended condition of use, no State or political subdivision may, after the date of publication of such determination, establish or continue in effect any requirement that applies to such chemical substance under the intended conditions of use considered, and addresses health endpoints considered, by the Administrator in the risk evaluation under section 6(b), and is designed to protect against exposure to such chemical substance under the intended conditions of use, unless the requirement of the State or political subdivision—"

Commented [A1]: There is already language that limits the scope of preemption to the intended uses considered by EPA. The additional language suggested in TA ("health endpoints") could be added here.

"(C) if the Administrator imposes a requirement, through a rule or order under section 5 or 6, that applies to a chemical substance or mixture (other than a requirement described in section 6(a)(6)) and is designed to protect against a risk of injury to health or the environment associated with such chemical substance or mixture, no State or political subdivision may, after the effective date of such requirement, establish or continue in effect any requirement that applies to such chemical substance or mixture (including a requirement that applies to an article because the article contains the chemical substance or mixture) and is designed to address health endpoints considered by the Administrator arising from ~~protect against~~ exposure to the chemical substance or mixture either under the intended conditions of use considered by the Administrator in the risk evaluation under section 6(b) or from such~~e~~ uses identified in a notice received by the Administrator under section 5(a) as were the subject of the requirement imposed, or, in the case of a requirement imposed pursuant to section 6(i), is designed to protect against a risk of injury considered by the Administrator in imposing such requirement, unless the requirement of the State or political subdivision—"

Commented [A2]: This avoids preemption on uses in the PMN that were never the subject of a requirement, since the general theory of preemption in this paragraph seems to be predicated on EPA having imposed a requirement. If the drafters wished to assign a preemptive impact to the "not likely to present an unreasonable risk" finding added to section 5 by the December 15 discussion draft, that would be better handled under B.

Commented [A3]: This reason for this broader preemption is presumably because there is no EPA risk evaluation for a PBT that is directly regulated under 6(i).

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 1/5/2016 2:24:52 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA Request on Unreasonable Risk - SECTION 4 AND SECTION 6

Michal – thanks for the reminder. On my tracking list for you are:
- unreasonable risk (below)
- cost considerations

Any others? We're meeting shortly to review where we are on the requests, both of which are already in progress. Thanks,
Sven

Sven-Erik Kaiser
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202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, January 05, 2016 9:20 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Request on Unreasonable Risk - SECTION 4 AND SECTION 6

And there is also this one. Thanks.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
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202-224-2742

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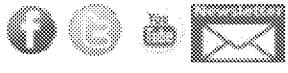

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, December 23, 2015 1:00 PM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA Request on Unreasonable Risk - SECTION 4 AND SECTION 6

Michal,
I'll be glad to circulate. The TSCA team is connected electronically and we're also working on the previous requests. Please let me know any additional questions. Happy holidays,
Sven

On Dec 23, 2015, at 12:52 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Sven – just checking in to see whether this formulation works to address the catch-22? And if not, can you suggest a better formulation? No worries if relevant staff are out of the office, early in the new year is fine for response.

SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.

(a) TESTING REQUIREMENTS.—If the Administrator finds that—

(1)(A)(i) there is a basis for concern that the manufacture, distribution in commerce, pro-cessing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

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<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, December 16, 2015 5:35 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on Unreasonable Risk - SECTION 4 AND SECTION 6

Michal,
This responds to your technical assistance request on "unreasonable risk." Please let me know if any questions. Thanks,
Sven

Question: If the section 4 test finding catch 22 was removed or changed to something like "basis for concern" or something like that, under House text, would EPA be able to request some data from industry on a chemical that was ubiquitous but about which little was known in order to establish some potential for hazard (and then be able to proceed with a risk evaluation)? I don't think I read the House bill as allowing this, I think I read it as allowing testing once a risk evaluation is already underway. But if so, would EPA be likely to use its section 4 authority and resources that way, or would it be more likely to use it on substances for which the "may pose an unreasonable risk" section 6 finding could more easily be made?

EPA Response: TSCA section 4 provides two bases for requiring testing: a finding the a chemical substance may present unreasonable risk (4(a)(1)(A)), and a finding based on production volume, release and/or exposure (4(a)(1)(B)). You previously asked whether the section 4 findings could be made for ubiquitous chemicals, and our answer was that they likely could under (B), but only for chemicals manufactured at substantial volumes. We understand that you now want to know if a change to the (A) findings would provide another, perhaps more certain, basis to require testing for ubiquitous chemicals.

We think it would, if by "ubiquitous" you mean a chemical with widespread exposure. If the (A) finding were changed to require only a showing that EPA has a basis for concern, we believe that language – plus the fact that Congress intentionally moved away from the "may present" standard – would give EPA a good basis to require testing of such a chemical in the absence of information demonstrating that the chemical posed little or no hazard. EPA would still need to show that there are insufficient data and experience as to the chemical to enable the Agency to determine or predict the effects of the chemical, and that testing is necessary to close the data gaps – findings that EPA must make under both (A) and (B) (4(a)(1)(A)(ii) and (iii), 4(a)(1)(B)(ii) and (iii)). But, again, for a chemical with widespread exposure, we think EPA would most likely be able to

demonstrate a basis for concern so long as the Agency could show that there were open questions about hazard.

You also suggest the possibility of simply dropping the "may present" standard, rather than replacing it. We don't think that would make sense, since the (A) basis for testing would have no function if it contained no standard.

Finally, you asked whether or not EPA would be likely to use section 4, if given the authority, to help clear the hurdle to initiating a risk evaluation under section 6 of the House bill. We would not want to rule out this use of section 4 authority, but think such use would be fairly minimal, particularly in the earlier years of implementation when the focus would be on TSCA Work Plan chemicals and other chemicals that for which there is some information. EPA would interpret the bar for initiating a risk evaluation on non-Work Plan chemicals under 6(b)(3)(A)(i) as fairly low. The House language requires that EPA make a finding that the chemical substance "may present an unreasonable risk," but that finding is based on potential hazard and a potential route of exposure. We interpret this as not requiring actual or documented hazard/exposure information. And because we don't anticipate the 6(b)(3)(A)(i) finding to be a significant barrier to initiating risk evaluations, we also don't anticipate a regular need to invoke section 4 testing authority to overcome it. A more likely use of section 4 would be to support necessary analysis during the risk evaluation, and ultimately, a determination of whether or not the chemical substance "presents or will present…an unreasonable risk."

Sven-Erik Kaiser
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202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Sunday, December 06, 2015 9:53 AM
To: Distefano, Nichole <DiStefano.Nichole@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Subject: TA request (for starting on Monday)

Nichole

We've very much appreciated the rapid turn around on questions related to the "may pose an unreasonable risk" section 4 and 6 text of House/TSCA, as well as efforts to understand what it could mean for EPA to have to determine both potential exposure and potential hazard under section 6 before starting a risk evaluation.

I'm trying to understand whether the solution on section 6 could be in section 4.

If the section 4 test finding catch 22 was removed or changed to something like "basis for concern" or something like that, under House text, would EPA be able to request some data from industry on a chemical that was ubiquitous but about which little was known in order to establish some potential for hazard (and then be able to proceed with a risk evaluation)? I don't think I read the House bill as allowing this, I think I read it as allowing testing once a risk evaluation is already underway. But if so, would EPA be likely to use its section 4 authority and resources that way, or would it be more likely to use it on substances for which the "may pose an unreasonable risk" section 6 finding could more easily be made?

Thanks

Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/10/2015 7:53:12 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Hunt, Jasmine (Durbin) [Jasmine_Hunt@durbin.senate.gov]; Joseph, Avenel (Markey) [Avenel_Joseph@markey.senate.gov]
Subject: RE: Senate TSCA TA on State Preemption and Science

Michal,
This responds to your revised TA request. Please let me know if any questions. Thanks,
Sven

Text revised to: (1) Delete an unnecessary comma and (2) Conform the discussion of best available science to the 3A formulation of "consistent with", and (3) Make clearer, by adding two commas, that the various science requirements apply to the risk, not the use. We note that you have added new language about "supporting studies conducted in accordance with sound and objective scientific practices" which does not appear in the particular paragraph 3(A)(c)(3)(A). We presume this was an intentional decision to depart from 3(A)(c)(3)(A) as your model.

"In the judgment of the Administrator, the requirement of the state or political subdivision of the state, is designed to address a risk of a chemical substance, under the conditions of use, that was identified ~~using~~ **consistent with** the best available science, **using** supporting studies conducted in accordance with sound and objective scientific practices, and **based on** the weight of the scientific evidence."

Sven-Erik Kaiser
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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, July 10, 2015 1:35 PM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW); Hunt, Jasmine (Durbin); Joseph, Avenel (Markey)
Subject: RE: Senate TSCA TA on State Preemption and Science

Thanks. also playing with this one, following your earlier feedback that the cite to the policies, practices and guidance section was odd. Still work given stated intent?

In the judgment of the Administrator, the requirement of the state or political subdivision of the state, is designed to address a risk of a chemical substance under the conditions of use that was identified using the best available science, supporting studies conducted in accordance with sound and objective scientific practices, and the weight of the scientific evidence.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations

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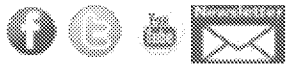
Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, July 10, 2015 1:31 PM
To: Freedhoff, Michal (Markey)
Cc: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW); Hunt, Jasmine (Durbin); Joseph, Avenel (Markey)
Subject: RE: Senate TSCA TA on State Preemption and Science

Michal,
This responds to your followup TA request on state preemption and science. Your alternative drafting is clear, and we agree that it would accomplish your stated goal. Please let me know if any additional questions.
Thanks,
Sven

Sven-Erik Kaiser
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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, July 10, 2015 9:19 AM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW); Hunt, Jasmine (Durbin); Freedhoff, Michal (Markey); Joseph, Avenel (Markey)
Subject: RE: Senate TSCA TA on State Preemption and Science

Thank you

No intentional removal of the "based on the judgement" language, was just sending the replacement portion of the provision.

I'm not certain your version works exactly. Intent was to tie the science finding to the "risk" and have a requirement that the state action is designed to meet the risk but not be tied to the same science finding. Do you think this quickly drafted alternative could work?

YOURS:

"In the judgment of the Administrator, the statute or administrative action of the state or political subdivision of the state is designed to address a risk of a chemical substance under the conditions of use and is the product of decision-making that is of a quality comparable to that specified under section 3A(c)(3)(A)."

ALTERNATIVE:

"In the judgment of the Administrator, the statute or administrative action of the state or political subdivision of the state, is designed to address a risk of a chemical substance under the conditions of use that was identified using decision-making that is of a quality comparable to that specified under section 3A(c)(3)(A)."

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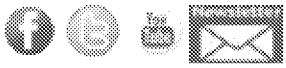

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, July 10, 2015 7:46 AM
To: Freedhoff, Michal (Markey)
Cc: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW); Hunt, Jasmine (Durbin)
Subject: Senate TSCA TA on State Preemption and Science

Michal,
This responds to your TA request.

Was the deletion of the phrase "based on the judgment of the Administrator" intentional? The presence or absence of this phrase affects the degree of discretion that EPA would have in making decisions on these waivers.

3(A)(c)(3)(A) is not itself a description of a particular kind of information. It is a directive to ensure that policies, procedures, and guidance ensure that EPA engages in a particular kind of decision-making. The decision-making rubric includes factors other than the quality of the information upon which the decision was made (e.g, whether EPA properly weighted and analyzed the information)

A potentially clearer way of expressing your intentions:

"[In the judgment of the Administrator], the statute or administrative action of the state or political subdivision of the state is designed to address a risk of a chemical substance under the conditions of use and is the product of decision-making that is of a quality comparable to that specified under section 3(A)(c)(3)(A)."

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

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On Jul 9, 2015, at 1:09 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

We will also need some TA on the language below, which is a potential alternative to the science prong on the section 18a waiver. Basically trying to say "the science about the risk is solid, and the state requirement is designed to address that risk".

The statute or administrative action of the state or political subdivision of the state is designed to address a risk of a chemical substance under the conditions of use that is based on information that is consistent with section 3(A)(c)(3)(A)

From: Kaiser, Sven-Erik
Sent: Thursday, July 9, 2015 12:03 PM
To: Black, Jonathan (Tom Udall)
Cc: Karakitsos, Dimitri (EPW); Freedhoff, Michal (Markey); Hunt, Jasmine (Durbin)
Subject: Re: Senate TSCA TA Call on Fees and Budget

Yes- 1pm- call 866-299-3188, code 202-566-2753#. Thanks,
Sven

On Jul 9, 2015, at 11:45 AM, "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov> wrote:

Our plan is to call at 1.

From: Kaiser, Sven-Erik
Sent: Wednesday, July 8, 2015 5:35 PM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW); Freedhoff, Michal (Markey); Hunt, Jasmine (Durbin)
Subject: Senate TSCA TA Call on Fees and Budget

Jonathan,
I'm getting folks together, let's say tentatively a call tomorrow, Thurs, July 9 at 1pm. Let me know if the time moves. Please call 866-299-3188, code 202-566-2753#. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Wednesday, July 08, 2015 4:01 PM
To: Kaiser, Sven-Erik
Cc: Karakitsos, Dimitri (EPW); Freedhoff, Michal (Markey); Hunt, Jasmine (Durbin); Black, Jonathan (Tom Udall)
Subject: EPA T.A. Call on TSCA Fees and Budget

Sven, we are meeting from 1130-2pm tomorrow. One of the topics of discussion will be TSCA fees and the budget, specifically, how to key the minimum appropriations to ensure that EPA can set user fees.

We'd like to know how OMB A11 intersects with the budgeting and what is covered in the TSCA office.

Our preference is to call in around 1pm if possible. We'd also like to include Dem and GOP Senate Appropriations staff.

Others can chime in about the things they'd like to ask about.

Thanks,
---Jonathan

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 1/4/2016 10:41:35 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request - 8 questions
Attachments: Markey.TSCA TA.8 questions.docx

Michal – in response to your request, see attached EPA's technical assistance. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, December 17, 2015 12:31 PM
To: Distefano, Nichole <DiStefano.Nichole@epa.gov>
Subject: TA request

Hi Nichole

I was hoping to get responses to the following questions:

1) The safety standard approach in this bill uses underlying TSCA's "unreasonable risk" lexicon. In the changes to TSCA section 6, EPA is told not to include costs or other non-risk factors, which presumably allows EPA to make chemical safety decisions exclusively using scientific risk assessments. Do you agree with my assessment of this as far as Section 6 goes? Does EPA also believe that this bill ensures that EPA cannot consider costs or other non-risk factors in other sections of TSCA, and if not, why not? Does this bill address in totality throughout TSCA the "unreasonable risk" argument that was used to overturn the asbestos ban?
2) Does EPA have the authority it needs under this bill to require testing of chemicals? Is the current TSCA catch-22 test finding which requires EPA to find that there may be an unreasonable risk BEFORE requiring such testing removed in this language?
3) Does EPA have sufficient flexibility in this bill to appropriately consider costs of rulemaking, while also ensuring that it will not have undue litigation risk or incur analytic burden if it does not find that a cost-effective regulatory option that will address the risk the chemical poses exists?
4) Is EPA required to assess the safety of a new chemical on vulnerable subpopulations under this bill?
5) Does this text give EPA the clear authority to set priorities for conducting risk evaluations that allows EPA to study chemicals that are ubiquitous OR known/suspected hazards? Are there deadlines that are enforceable for EPA to conduct its chemical safety responsibilities in this bill?
6) Does this bill require manufacturers to substantiate new and old CBI claims? Can data relevant to health and safety be treated as CBI under this bill? Does EPA have authority under this bill to provide CBI to state and local governments when necessary?
7) Does this bill ensure that EPA will get sufficient industry and other resources to fund its TSCA activities? How does this bill's funding for EPA intersect with the ability for industry to request that EPA perform risk evaluations under the bill?

8) Does the bill give EPA the mechanisms and authorities to expeditiously target chemicals of concern and promptly assess and regulate new and existing chemicals?

Thanks
Michal

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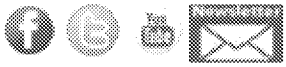

1) The safety standard approach in this bill uses underlying TSCA's "unreasonable risk" lexicon. In the changes to TSCA section 6, EPA is told not to include costs or other non-risk factors, which presumably allows EPA to make chemical safety decisions exclusively using scientific risk assessments. Do you agree with my assessment of this as far as Section 6 goes? Does EPA also believe that this bill ensures that EPA cannot consider costs or other non-risk factors in other sections of TSCA, and if not, why not? Does this bill address in totality throughout TSCA the "unreasonable risk" argument that was used to overturn the asbestos ban?

EPA Response: We agree that section 6(b) requires EPA to conduct risk evaluations exclusively using scientific risk assessments, without consideration of cost or other non-risk factors. We also believe it is quite clear that the level of risk reduction required for rules under section 6(a) following section 6(b) risk evaluations is to be determined without regard to cost (except where EPA issues a critical use exemption under section 6(h)).

EPA does not believe the bill ensures that EPA cannot consider cost or other non-risk factors in applying the "unreasonable risk" standard in other parts of TSCA. A congressional choice to expressly change the operation of the term in section 6 only – especially in light of the global changes in the Senate bill – could support an argument that Congress intended to leave the operation of the standard unchanged elsewhere. This argument might be bolstered by TSCA section 2(c) – unchanged in the House bill, again in contrast to the Senate bill – which requires EPA to "consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take" under TSCA.

With respect to the arguments that were used to overturn the asbestos ban, we believe the bill does address those in the section 6 context. However, if EPA were to act under section 7, for example, to address a chemical risk, similar arguments could be made.

2) Does EPA have the authority it needs under this bill to require testing of chemicals? Is the current TSCA catch-22 test finding which requires EPA to find that there may be an unreasonable risk BEFORE requiring such testing removed in this language?

EPA Response: EPA believes that this catch-22 is significantly ameliorated, although not completely eliminated, by the bill. The bill would add a new basis for EPA to require testing: as "necessary to conduct a risk evaluation under section 6(b)" (sec 4(a)(1)(C)). EPA is authorized to conduct a risk evaluation for a chemical if it determines that it "may present an unreasonable risk of injury to health or the environment *because of potential hazard and a potential route of exposure* under the intended conditions of use" (6(b)(3)(A)(i)) (emphasis added)). The italicized language – which does not appear in the "may present" basis for tesing under current TSCA – will presumably signal a lower bar than the current TSCA "may present" bar. That said, EPA would have to make the finding, and it would specifically need to have a reasonable basis for finding potential hazard and a potential route of exposure.

3) Does EPA have sufficient flexibility in this bill to appropriately consider costs of rulemaking, while also ensuring that it will not have undue litigation risk or incur analytic burden if it does not find that a cost-effective regulatory option that will address the risk the chemical poses exists?

EPA Response: EPA may have sufficient flexibility under the bill, but there is uncertainty given the drafting of section 6(c)(1)(B). We see two issues with the drafting of this provision. 1. If the intent is

that EPA's analysis to identify cost-effective options should be bounded by the information required to be considered during section 6(a) rulemaking under section 6(c)(1)(A), that could be stated more clearly. As drafted, the bill could be interpreted to require extensive analysis to identify all cost-effective options before EPA can select a non-cost-effective option, since EPA can select such an option only if it determines that "additional or different" (i.e., non-cost-effective) requirements are necessary, which might be difficult to do if EPA has not identified all cost-effective options. 2. Section 6(c)(1)(B) provides that EPA can select a non-cost-effective option if it is "necessary to protect against the identified risk." If the intent is to provide that such an option is necessary to meet the rulemaking standard under section 6(a), then the section 6(a) standard should be used here, rather than the alternative phasing.

4) Is EPA required to assess the safety of a new chemical on vulnerable subpopulations under this bill?

EPA Response: This, too, is not clear. EPA would be required to determine under section 5 that a chemical "is not likely to present an unreasonable risk of injury to health or the environment" before manufacture of a new chemical substance or manufacture or processing of a chemical substance for a significant new use could commence. With respect to existing chemicals, section 6(b)(4)(A) requires EPA to integrate and assess information on all intended uses when conducting a risk evaluation, "including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed subpopulations." If EPA determines that a chemical presents or will present an unreasonable risk, the required section 6(a) rule must ensure no unreasonable risk, "including an identified unreasonable risk to a potentially exposed subpopulation." EPA cannot find that a chemical will not present an unreasonable risk if it determines that the chemical "presents an unreasonable risk of injury to one or more potentially exposed subpopulations".

The absence of reference to exposed subpopulations in section 5 could be cited as a basis to argue that EPA is not required to consider such populations in its section 5 assessments. On the other hand, it could be argued that the section 5 analysis is intended to produce a prediction of how the chemical would fare under section 6, and that this cannot be done without some consideration of potentially exposed subpopulations.

5) Does this text give EPA the clear authority to set priorities for conducting risk evaluations that allows EPA to study chemicals that are ubiquitous OR known/suspected hazards? Are there deadlines that are enforceable for EPA to conduct its chemical safety responsibilities in this bill?

EPA Response: The bill gives EPA authority to set priorities for which chemicals to examine first – there is no such express authority, but express authority is not needed. That having been said, the authority specifically to "set priorities for conducting risk evaluations" is less clear for the reasons discussed in answer to question 2: EPA cannot conduct a risk evaluation without first finding that a chemical "may present an unreasonable risk of injury to health or the environment because of potential hazard and a potential route of exposure under the intended conditions of use", section 6(b)(3)(A)(i), and EPA has no express authority to require testing to aid in making this determination. EPA might be able to require testing of a ubiquitous chemical under section 4(a)(1)(B), but only if the chemical is "produced in substantial quantities" (generally interpreted as one million pounds per year). If a

chemical has known or suspected hazards, that should enable EPA to make the potential hazard portion of the section 6(b)(3)(A)(i) finding, but would still need to find a potential route of exposure.

In terms of deadlines: clear deadlines kick in once EPA determines that a chemical presents or will present an unreasonable risk, based on a risk evaluation. EPA must issue a proposed section 6(a) rule within one year of this finding, and a final rule within two years, with no opportunity of extension. (Section 6(b)(5)(C)). However, the bill does not contain clear, enforceable deadlines for EPA to conduct risk evaluations. The bill specifies that EPA shall initiate 10 or more risk evaluations in each fiscal year, but this obligation is "subject to the availability of appropriations" (section 6(b)(7)). This proviso gives EPA substantial discretion. Moreover, although the bill sets deadlines for EPA to complete risk evaluations (in general, three years for EPA-initiated evaluations and two years for industry-requested evaluations (section 6(b)(5)(A)), with extension of up to two years (section 6(b)(5)(B)), if EPA receives more industry requests than it has resources to conduct by the applicable two-year deadline, EPA "shall initiate risk evaluations that exceed the Administrator's allotted resources as soon as resources for such resources are available" (section 6(b)(5)(B)(i)). This appears to allow EPA to extend the deadline for either EPA-initiated or industry-requested risk evaluations if it receives a surplus of industry requests.

6) Does this bill require manufacturers to substantiate new and old CBI claims? Can data relevant to health and safety be treated as CBI under this bill? Does EPA have authority under this bill to provide CBI to state and local governments when necessary?

EPA Response: The bill (section 14(c)(1)(A)(i)) would require manufacturers and others submitting CBI claims after the date of the FRL to substantiate them. It would not require substantiation of existing CBI claims.

In general, as with current TSCA, the bill would preclude confidential treatment of health and safety studies and data from such studies. However, it expands the types of such information that can be protected as CBI, by providing that data that discloses formulas (including chemical structure) can be treated as CBI, even if in a health and safety study (section 14(b)(1)). Currently, formula information in health and safety studies can be protected as CBI only if it discloses process information.

The bill does give EPA authority to provide CBI to state and local governments when necessary (section 14(a)(5)). That said, EPA would not be able to disclose CBI to state and local governments as quickly as it can disclose CBI in the other circumstances identified in section 14(a). TSCA generally imposes a 30-day period following notification before EPA can disclose CBI, but it creates an exception to this waiting period for information disclosed under the grounds specified in section 14(a). The bill would not add disclosure under section 14(a)(5) to the list of exceptions (although it would add disclosure to responders and health professionals under the new section 14(a)(6)).

7) Does this bill ensure that EPA will get sufficient industry and other resources to fund its TSCA activities? How does this bill's funding for EPA intersect with the ability for industry to request that EPA perform risk evaluations under the bill?

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

EPA Response: The bill would require that industry requestors fully fund requested risk evaluations (sections 6(b)(4)(F) and 18(b)(C)(3)). However, the bill does not provide for fees to cover the cost of any rulemaking required under section 6(a) following an industry-requested evaluation, or for fees to cover the cost of EPA-initiated risk evaluations or the cost of any rulemaking needed following such evaluations.

With respect to the intersection between funding and industry-requested evaluations: as a practical matter, the fact that, on the one hand, fees will cover the cost of industry-requested evaluations, but, on the other hand, no provision provides for fees to cover EPA-initiated evaluations or risk management activities might create a dynamic under which industry-requested evaluations have an advantage under the section 6(b)(5)(B)(i) prioritization process (see answer 5). This dynamic could be amplified by the provision that, in adjusting deadlines under this provisions, EPA must take into account "the requirement in paragraph 6(b)(4)(F)" – i.e., the requirement for manufacturers to fund manufacturer-requested risk evaluations. Under this provision, EPA might have a weaker basis for deferring manufacturer-requested evaluations based on resource considerations than for deferring EPA-initiated evaluations. Cutting against this concern is the provision that not more than 50% of all risk evaluations can be industry-initiated evaluations (section 6(b)(8)).

8) Does the bill give EPA the mechanisms and authorities to expeditiously target chemicals of concern and promptly assess and regulate new and existing chemicals?

EPA Response:

With respect to existing chemicals, see answers 5 and 7.

With respect to new chemicals, see answer 4. In addition, although the bill would provide a clear bar to manufacture of a new chemical or manufacture or processing of an existing chemical for a new use absent an EPA finding that the chemical is not likely to present an unreasonable risk, EPA's authority under the bill to expeditiously regulate chemicals for which EPA cannot make the finding is less clear. (This will not likely result in risks to health or the environment, since manufacture and processing are barred absent the EPA finding; but it may result in situations in which EPA cannot make the finding and lacks authority to regulate in order to be able to make the finding.)

Under current TSCA, EPA can regulate a new chemical under either section 5(e) or 5(f). These authorities make sense under current TSCA where the burden is on EPA to regulate or stop a new chemical or use, but work less well where an affirmative EPA finding is needed for a chemical to complete the section 5 process.

Section 5(e) gives EPA authority to issue administrative orders or initiate judicial actions for new chemicals that may present unreasonable risk. However, section 5(e) does not mesh well with the new section 5(a)(1) provision, for at least three reasons. 1. EPA can issue a section 5(e) order or initiate a section 5(e) court action only if available information is insufficient to permit a reasoned evaluation of the health effects (section 5(e)(1)(A)(i)). Thus, this authority is not available if EPA has sufficient information to determine that a chemical will present an unreasonable risk, or simply has insufficient time during the section 5 review period to complete analyses that would enable EPA to clear the chemical without restriction. 2. EPA cannot issue a section 5(e) order later than 45 days

before the expiration of the section 5 review period (section 5(e)(1)(B)). If EPA did not act during this period, it would not be able to issue a section 5(e) order to restrict the chemical in a way that would enable the Agency to make the "not likely to present" finding. 3. The section 5(e) standard – may present an unreasonable risk – does not necessarily seem to be the inverse of the new section 5(a) – that a chemical is not likely to meet the safety standard.

Section 5(f) gives EPA authority to rapidly regulate a new chemical for which EPA has sufficient information and concludes that the chemical presents or will present an unreasonable risk, through the issuance of a proposed section 6 rule or commencement of a court action prior to the expiration of the section 5 notice period. Because it is very difficult to develop a proposed section 6 rule or a court case during this period, EPA has never used this authority – instead, it routinely uses the section 5(e) authority. Section 5(f) seems superfluous in light of the new finding required under section 5(a), since inaction by EPA would prevent manufacture or processing.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/10/2015 7:30:32 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA on State Preemption Waiver - Compelling/Prevailing

Michal,
"Prevailing" seems to require just that the state or local conditions currently exist, with no assessment of significance or magnitude. We have no technical objection to that term, other than to point out that it arguably adds no meaning in context. Thanks,
Sven

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, July 10, 2015 2:49 PM
To: Kaiser, Sven-Erik
Subject: Re: Sen. Markey TSCA TA on State Preemption Waiver - Compelling

Thanks. Any views on "prevailing"?

From: Kaiser, Sven-Erik
Sent: Friday, July 10, 2015 2:40 PM
To: Freedhoff, Michal (Markey)
Subject: RE: Sen. Markey TSCA TA on State Preemption Waiver - Compelling

Michal,
In response to your TA request, we do not have any insight as to how various words might have been interpreted by courts -- that would involve some legal research that we have not done. However, the term "substantial" seems to be a softer alternative to "compelling". "Substantial" is defined in Black's Law Dictionary as, among other things, "actually existing; real; not seeming or imaginary". "Compelling" is not defined in Black's, but it's defined in American Heritage as "urgently forceful". "Significant" might be viewed as being in the middle, defined by American Heritage as meaning, among other things, "fairly large in amount of quantity".

Please let me know if any additional questions and if helpful we're available for a call until 4:30 today. Thanks,
Sven

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202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, July 10, 2015 1:32 PM

To: Kaiser, Sven-Erik
Subject: RE: Sen. Markey TSCA TA on State Preemption Waiver - Compelling

We're aware that similar constructs exist in other environmental statutes, and that in those statutes it makes sense. If you're in the northeast, you can prove that your air quality is worse and should be determined to be a "compelling local" problem because Ohio air blows your way. If your State has some particular water issue, you can make this sort of language work for that localized problem too.

The problem in the toxics context is that you can't really show that the flame retardants in kids pajamas harm the kids in your state more than they harm kids in other states. The concern is that while the word "local" has been litigated in an OSHA case related to Prop 65 to not mean "unique", there really isn't an understanding of what "compelling" means in this situation and it seems like a very strong word to use. Perhaps if there is case law that is on point with "compelling" in the CWA context that might help me (as opposed to case law being about the word "extraordinary"), but additionally, if there is another word/phrase that might be a bit softer and/or also understood via case law to be a bit softer, that would be helpful too.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
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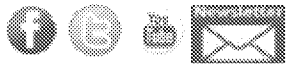
Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, July 10, 2015 1:25 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on State Preemption Waiver - Compelling

Michal,
We need a better understanding of your goal before we can suggest alternate drafting. Is your goal to change the wording without changing the substantive operation of the provision? Or are you seeking to change the wording in order to bring about a particular substantive change? If the latter, what is your substantive objective? Maybe a quick note or call would be helpful to sort it out.

Note also that the current drafting is a variation of the standard that applies for a preemption waiver under Section 209 of the Clean Air Act: whether the waiver is needed "to meet compelling and extraordinary conditions." That language has been applied by the agency and courts for decades.

Thanks,
Sven

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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, July 09, 2015 5:04 PM
To: Kaiser, Sven-Erik
Subject: on a separate TA track

Also on preemption, I am trying to see whether there are other words besides "compelling" might exist for what is below. Particularly words that have an understood meaning via case law, regulation or in some other statute.

> "(A) compelling State or local conditions warrant granting the waiver to protect health or the environment;

Michal Ilana Freedhoff, Ph.D.
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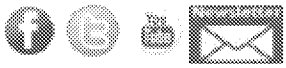
Connect with Senator Markey



Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/27/2015 9:44:22 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: RE: Udall, Whitehouse, Merkley, Booker Announce Breakthrough Improvements to Landmark Chemical Safety Bill

thanks

Sven-Erik Kaiser
U.S. EPA
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Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, April 27, 2015 5:40 PM
To: Jones, Jim; Kaiser, Sven-Erik
Subject: FW: Udall, Whitehouse, Merkley, Booker Announce Breakthrough Improvements to Landmark Chemical Safety Bill

From: Tom Udall Press Office
Sent: Monday, April 27, 2015 5:34 PM
To: Tom Udall Press Office
Subject: Udall, Whitehouse, Merkley, Booker Announce Breakthrough Improvements to Landmark Chemical Safety Bill

NEWS FROM
The United States Senate

FOR IMMEDIATE RELEASE
Monday, April 27, 2015

Contacts:
Jennifer Talhelm (Udall), 202.228.6870, news_pressoffice@tomudall.senate.gov
Seth Larson (Whitehouse), seth_larson@whitehouse.senate.gov
Ray Zaccaro (Merkley), 202.224.3753 ray_zaccaro@merkley.senate.gov
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Udall, Whitehouse, Merkley, Booker Announce Breakthrough Improvements to Landmark Chemical Safety Bill

Agreement strengthens protections, gives states greater power to restrict chemicals and enforce laws

WASHINGTON — Today, **Democratic U.S. Sens. Tom Udall (N.M.), Sheldon Whitehouse (R.I.), Jeff Merkley (Ore.)** and **Cory Booker (N.J.)** announced a major breakthrough agreement in historic legislation to reform the nation's broken chemical safety law, a day before a "markup" hearing to finalize the legislation in the Senate Environment and Public Works Committee. Following intense weekend negotiations, the bipartisan compromise agreement strengthens protections under the proposed law and expands states' authority. It is the latest sign that support is continuing to grow for the Frank R. Lautenberg Chemical Safety for the 21st Century Act, authored by Udall and Sen. David Vitter (R-La.), which would finally ensure the American people are protected from chemicals sold in everyday products and used in manufacturing.

"I am extremely pleased to join Senators Whitehouse, Merkley and Booker to announce this agreement. I thank them — as well as Senator Vitter — for their dogged commitment to working with us and continuing to strengthen this bipartisan bill," **Udall said.** "Thirty-nine years is too long to wait for a working chemical safety law that protects our families and communities in New Mexico and across the country. But finally, momentum is building for common-sense legislation to finally ensure our kids are safe from dangerous chemicals. I am very optimistic that we can pass this bill out of committee and bring it to the Senate floor and that support will keep growing in the coming days and weeks."

"The Toxic Substances Control Act is badly outdated and has failed to protect public health and the environment from toxic chemicals for decades," **said Whitehouse.** "We now have an historic opportunity to update and improve the law, and I believe the agreement announced today will help give American families peace of mind that everyday products we rely on are safe. I thank Senators Udall, Vitter, and Inhofe for their leadership on this issue and for working with me and other Senators to address our concerns."

"This bipartisan agreement greatly strengthens the ability of states to protect citizens from toxic chemicals when the federal government has failed to do so," **Merkley said.** "It's a vast improvement over the broken law currently in force and an important step in protecting families across America."

"I am proud that we have secured important changes to the Frank Lautenberg Chemical Safety Act that will strengthen and streamline EPA's ability to regulate toxic chemicals while still allowing states to have significant authority to regulate potentially harmful substances," **Booker said.** "While this bill represents a compromise and is not perfect, the bipartisan consensus we have attained is a significant step forward in long-stalled efforts to improve federal chemical safety protections. Senator Frank Lautenberg made strengthening federal laws to better protect Americans from toxic substances and pollutants one of his top priorities, working tirelessly to find common ground across party lines to advance important reforms of the Toxic Substances Control Act. Reaching a bipartisan agreement to improve the legislation bearing his name is a fitting way to honor this great New Jerseyan's legacy."

The Udall-Vitter bill would overhaul the 1976 Toxic Substances Control Act, which was gutted by a 1991 court decision that found the Environmental Protection Agency (EPA) lacked the ability to ban even asbestos. The Lautenberg Chemical Safety for the 21st Century bill would require EPA to consider only the health and safety impacts of a chemical — never the cost or burden to manufacturers — when assessing chemicals for safety. It ensures special protections for those most vulnerable from chemicals — defined in the bill as pregnant women, infants, the elderly and chemical workers. It sets a new fee so chemical companies will bear a larger share of the cost of evaluating and regulating chemicals. And it provides certainty in the law about when states may step in if EPA does not act to regulate or ban dangerous chemicals.

The compromise agreement was incorporated into the underlying bill and senators will vote on it at tomorrow's markup. The agreement addresses some of the concerns that have been raised about the legislation, including when state actions would be preempted by the EPA and how states would be allowed to enforce the law. The changes strengthen protections for American consumers by making it clear that states may act to regulate a chemical if EPA

misses required deadlines. It also ensures that states will get waivers to act on chemicals while EPA is evaluating them for safety. And it makes clear that states may co-enforce the law, with the condition that penalties may not be collected from both the state and the federal government for the same violation.

Further details of the agreement include:

The amendment clarifies when states may act after EPA begins evaluating a chemical:
Limitations on new state regulatory actions start when the scope of uses of a chemical is defined and end when the safety determination is made.
-If the deadline for the safety determination is missed, states are automatically granted a waiver from the "pause."
-EPA "shall" approve a state request for a waiver during the safety assessment if the states meet the following criteria:
The state requirement doesn't violate federal law,
The state requirement doesn't unduly burden interstate commerce, and
The state's concern about the chemical substance or the use of the chemical substance is based in peer-reviewed science.
-If EPA fails to make a decision on a state waiver within 90 days, the waiver is approved.
-The "automatic" approval of the waiver can be challenged, in which case the approval is suspended until a decision is reached, but if there is still no decision after a further 90 days, the waiver is again approved.

The date for state laws that are grandfathered under the law is moved back:
-Any state chemical regulation is permanently protected from preemption that is in effect before August 1, 2015. Previously, the grandfather date was January 1, 2015.

The amendment further clarifies pre-emption to state that:
-All state chemical disclosure laws are permanently protected from pre-emption.
-State clean air and clean water laws are not pre-empted.

State co-enforcement
-States will be allowed to co-enforce the law with condition that penalties can be collected from either the federal government or a state, but not both.

Regarding the designation of a chemical as "low priority" (not a significant health or safety threat), the amendment would allow:
-90 days of public comment for all listing decisions.
-Any member of the public to challenge a low priority decision within 60 days of listing.

The amendment lowers the bar for when a chemical can be designated as "high priority" (a significant health and safety threat). It states that:
-EPA shall designate a chemical as high priority based on "significant" [rather than "high"] hazard rather and "significant" [rather than "widespread"] exposure, and may designate a chemical as high priority if it has either characteristic.

For chemicals that are "persistent, bioaccumulative and toxic" (PBT):
-EPA must give preference to PBTs on the TSCA Work Plan for selecting chemicals on the initial high-priority list.
-Whether a chemical is a PBT is a required consideration for all high priority designations.
-EPA is required to select restrictions in risk management for PBTs that reduce exposure "to the maximum extent practicable"

The amendment requires expedited action on certain well-known chemicals. It states that:
-EPA will incorporate into safety assessments and determinations existing information regarding hazard and exposure published by other federal agencies or the National Academies, with the objective of increasing the efficiency of the safety assessments and determinations.

"Unreasonable risk" in the law

-In relevant places in TSCA, as amended by the bill, the term "unreasonable risk" is either clarified to exclude consideration of costs or other non-risk factors, or the word "unreasonable" is dropped.

The amendment clarifies the deadline for implementing restrictions and prohibitions by stating that:
-Compliance deadlines for risk management rules are to be "as soon as practicable." Bans and phase-outs are to be implemented "in as short a period as is practicable."

Imports section deleted
-The amendment deletes the imports section in order to maintain strict liability on importers that violate TSCA.

Industry petitioned chemicals — In addition to high-priority chemicals designated by EPA, manufacturers can petition EPA to designate additional chemicals for safety assessments and determinations.
-The industry would pay 100% of the cost of the assessment.
-There is no high priority pause whatsoever for Industry Petitioned Chemicals.
-These chemicals are in addition to the high priority list and do not limit the number EPA otherwise designates.
-These chemicals can amount to a minimum of 25% and a maximum of 30% of the cumulative total number of high priority chemicals. (So if EPA is evaluating 25 High Priority Chemicals, there could be an additional 6 to 8 industry-petitioned chemicals, which would allow EPA to review more chemicals than their resources would otherwise allow.)

Throughput of EPA work plan chemicals
-For chemicals that EPA has already identified as high-risk, manufacturers can petition for those chemicals to move to a safety assessment and determination, and pay 50% of the cost. EPA has full discretion to approve or deny these industry petitions.

Animal testing
-For the purposes of TSCA submissions to EPA, industry must look to scientifically reliable alternatives first before conducting new animal testing.

#########

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/10/2015 6:34:19 PM
To: 'Zipkin, Adam (Booker)' [Adam_Zipkin@booker.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Senate TSCA TA on Small Manufacturers Definition

Adam,
This responds to the TA request on defining small manufacturers. To be clear, no, EPA wasn't considering updating the definition of small manufacturer in the CDR rulemaking.

The primary reason why the small manufacturer definition is meaningful is because it affects who must report under CDR. That's why our last TA noted how we had considered potential small business impacts of the CDR using both the TSCA and the SBA definitions. The SBA participated in the interagency review process for that rulemaking.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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202-566-2753

From: Zipkin, Adam (Booker) [mailto:Adam_Zipkin@booker.senate.gov]
Sent: Friday, July 10, 2015 9:33 AM
To: Kaiser, Sven-Erik; Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW); Deveny, Adrian (Merkley)
Subject: RE: SEPW TSCA TA

Sven so that I am clear -- on #3 regarding small manufacturers, are you saying that in 2011 EPA considered updating/revising the 1984 definition and decided that no change was warranted? Was SBA consulted?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, July 02, 2015 9:29 AM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW); Zipkin, Adam (Booker); Deveny, Adrian (Merkley)
Subject: SEPW TSCA TA

Jonathan,
This technical assistance responds to several requests. The language on small manufacturers is in addition to earlier TA on the same subject. The technical assistance is intended for use only by the requesters. The technical assistance does not necessarily repr3esent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

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202-566-2753

1. Regarding the "denominator issue":

The following suggested redrafting is intended to effectuate what we understand to be the policy objective behind section 4A(c)(2)(A) without suggesting, as the current draft does, that "additional priorities" designated under 4A(c)(1) are a subset of high priority chemicals designated under subsections 4A(a)(2) or (b)(3). Our understanding of the policy objective is that, in calculating the number of additional priority chemicals, the denominator for the required 25%-30% range should be the number of high-priority chemicals designated under those subsections, not the total number of chemicals designated to undergo safety assessments and safety determinations. Redline is from the version voted out of Committee:

> Sec 4A(c)(2)(A) – if a sufficient number of additional priority requests meet the requirements of paragraph (1), **the number of substances designated to undergo safety assessments and safety determinations under the process and criteria pursuant to paragraph (1) shall be** not less than 25 percent, or more than 30 percent, of the cumulative number of substances designated to undergo safety assessments and determinations under **subsections (a)(2) and (b)(3).** ~~this section are substances designated under the process and criteria pursuant to paragraph (1).~~

2. Regarding imports:

- Following is the new text that you requested, addressing existing chemical substances that were added to the TSCA inventory, after a Section 5 determination that they were not likely to meet the safety standard. Such a determination would trigger restriction under 5(d)(4), which would be part of the basis for a new exception to the export exemption.
- This resolves the technical concern about an exported new chemical substance being made subject to TSCA under (A) and then ceasing to be subject to TSCA as soon as the chemical substance becomes an existing chemical subject to a section 5 order. Once the chemical is added to the Inventory, it would remain excepted from the export exemption, but now under (C) rather than under (A).
- This also provides that if domestic uses of a new chemical substance are restricted under a section 5 order, it would only take a "likely to present" finding, with respect to the exported volumes, to later make the exported volumes of such chemical substance subject to TSCA jurisdiction.

"(2) EXCEPTION.—Paragraph (1) shall not apply to—

"(A) any new chemical substance that the Administrator determines is likely to present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors; ~~or~~
"(B) any chemical substance that the Administrator determines presents or will present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors; **or**
"(C) any chemical substance that:

(i) **the Administrator determines is likely to present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors; and**

(ii) **is subject to restriction under section 5(d)(4)**

3. Regarding small manufacturers:

- For purposes of Chemical Data Reporting, the operative definition of "small manufacturer or importer" is found at 40 CFR 704.3. Chemical manufacturers that fall under this definition are generally exempt from reporting. 40

CFR 711.9. The standard used in the definition of "small manufacturer or importer" was established in 1984. 49 FR 45425. In 2011, EPA analyzed potential small business impacts of Chemical Data Reporting using both the SBA employee size standards and the TSCA sales-based definition of small business. 76 FR 50858.

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, June 29, 2015 2:06 PM
To: Kaiser, Sven-Erik; Karakitsos, Dimitri (EPW); Zipkin, Adam (Booker); Deveny, Adrian (Merkley)
Subject: RE: SEPW TSCA TA

Thanks! I'm glad someone is keeping track!

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, June 29, 2015 2:05 PM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW); Zipkin, Adam (Booker); Deveny, Adrian (Merkley)
Subject: SEPW TSCA TA

Jonathan,
I think there are 3 outstanding TA requests below. The first two are underway and included is the response to the small manufacturers definition question. Please let me know if any additional questions. Thanks,
Sven

– exports (EPA working on TA)

– cap on industry assessments (EPA to provide text change on p.22, line 18)

– small manufacturers definition

EPA response: most of EPA's TSCA programs, including CDR, use the same definition for small business as defined by regulation in 40 CFR 704.3. This definition has never been updated. A few TSCA programs use different definitions of small business, including for 8(a) PAIR and for calculating PMN fees.

Small manufacturer or importer means a manufacturer or importer that meets either of the following standards:

(1) *First standard.* A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $40 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer or importer is greater than 45,400 kilograms (100,000 pounds), the manufacturer or importer shall not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer or importer qualifies as small under standard (2) of this definition.

(2) *Second standard.* A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $4 million, regardless of the quantity of substances produced or imported by that manufacturer or importer.

(3) Inflation index. EPA shall make use of the Producer Price Index for Chemicals and Allied Products, as compiled by the U.S. Bureau of Labor Statistics, for purposes of determining the need to adjust the total annual sales values and for determining new sales values when adjustments are made. EPA may adjust the total annual sales values whenever the Agency deems it necessary to do so, provided that the Producer Price Index for Chemicals and Allied Products has changed more than 20 percent since either the most recent previous change in sales values or the date of promulgation of this rule, whichever is later. EPA shall provide Federal Register notification when changing the total annual sales values.

Sven-Erik Kaiser

U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, June 29, 2015 1:37 PM
To: Kaiser, Sven-Erik
Cc: Karakitsos, Dimitri (EPW); Zipkin, Adam (Booker); Deveny, Adrian (Merkley)
Subject: Follow-up

Hey Sven, sorry again to miss the call last week. My understanding was there might be one more follow-up on exports? Are we waiting for anything from EPA?

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/10/2015 5:33:01 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA on State Preemption Waiver - Compelling

Michal,
Thanks for the clarification. I'll get this to folks pronto. Best,
Sven

Sven-Erik Kaiser
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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, July 10, 2015 1:32 PM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Markey TSCA TA on State Preemption Waiver - Compelling

We're aware that similar constructs exist in other environmental statutes, and that in those statutes it makes sense. If you're in the northeast, you can prove that your air quality is worse and should be determined to be a "compelling local" problem because Ohio air blows your way. If your State has some particular water issue, you can make this sort of language work for that localized problem too.

The problem in the toxics context is that you can't really show that the flame retardants in kids pajamas harm the kids in your state more than they harm kids in other states. The concern is that while the word "local" has been litigated in an OSHA case related to Prop 65 to not mean "unique", there really isn't an understanding of what "compelling" means in this situation and it seems like a very strong word to use. Perhaps if there is case law that is on point with "compelling" in the CWA context that might help me (as opposed to case law being about the word "extraordinary"), but additionally, if there is another word/phrase that might be a bit softer and/or also understood via case law to be a bit softer, that would be helpful too.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, July 10, 2015 1:25 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on State Preemption Waiver - Compelling

Michal,
We need a better understanding of your goal before we can suggest alternate drafting. Is your goal to change the wording without changing the substantive operation of the provision? Or are you seeking to change the wording in order to bring about a particular substantive change? If the latter, what is your substantive objective? Maybe a quick note or call would be helpful to sort it out.

Note also that the current drafting is a variation of the standard that applies for a preemption waiver under Section 209 of the Clean Air Act: whether the waiver is needed "to meet compelling and extraordinary conditions." That language has been applied by the agency and courts for decades.

Thanks,
Sven

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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, July 09, 2015 5:04 PM
To: Kaiser, Sven-Erik
Subject: on a separate TA track

Also on preemption, I am trying to see whether there are other words besides "compelling" might exist for what is below. Particularly words that have an understood meaning via case law, regulation or in some other statute.

> "(A) compelling State or local conditions warrant granting the waiver to protect health or the environment;

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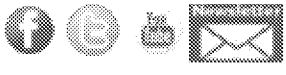
Connect with Senator Markey



Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/26/2015 9:31:19 PM
To: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
Subject: Re: Udall Inhofe TSCA TA on Articles

Line is open- Personal Phone / Ex. 6 code Personal Phone / Ex. 6

On Apr 26, 2015, at 5:24 PM, "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov> wrote:

Yes- use my call in Personal Phone / Ex. 6 code Personal Phone / Ex. 6 Thanks,
Sven

On Apr 26, 2015, at 5:19 PM, "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov> wrote:

Are folks available for a quick call at 5:30?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Sunday, April 26, 2015 04:43 PM
To: Karakitsos, Dimitri (EPW)
Cc: Black, Jonathan (Tom Udall)
Subject: Re: Udall Inhofe TSCA TA on Articles

Dimitri,
In response to your request, the consolidated language you sent over in your first email is fine, with one exception: in the section 5 language, the word "potential" should be inserted between "identified" and "risks". In PMN review, EPA identifies and reacts to potential risk; it does not do a full risk assessment and identify known risks. We had intended to include "potential" in our earlier email to you but apparently didn't do so -- sorry.

Re Richard Dennison's comments: We do not agree with his suggested changes to the SNUR language, for two reasons.

First, rather than requiring EPA to make an "affirmative finding" that the potential for exposure through articles warrants notification as our TA language did, Dennison's language would require EPA to "demonstrate" the potential for exposure through articles. We see that as a higher bar.

Second, as we interpret section 5(a), it automatically applies to chemicals in articles, for both SNUNs and PMNs, unless we exempt them. His drafting suggests otherwise and may be read to narrow the scope of section 5(a).

Some of his concerns in this regard are focused on the final sentence in our TA -- ie, **Nothing in this paragraph shall be construed to limit the Administrator's authority to exempt the import or processing of a chemical substance from requirements under 5(a)(1)(A).** Although we see some potential value to this sentence, it's not essential from our perspective and we don't see it as worth arguing over; so it could just be dropped.

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser
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On Apr 26, 2015, at 2:31 PM, "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov> wrote:

Before you get to far – Richard already raised some significant concerns on his end and I have attached a draft with his edits to the SNUR language.

I think it best at this point if you could please help with 2 things. First make sure our other provisions for Sections 5 and 6 are consistent with TA and second can we set up a call to discuss the overall language and the SNUR language with Richard and Mark Greenwood for some time this afternoon?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Sunday, April 26, 2015 1:54 PM
To: Karakitsos, Dimitri (EPW)
Cc: Black, Jonathan (Tom Udall)
Subject: Re: Udall Inhofe TSCA TA on Articles

Dimitri,
Got it- forwarding to folks. Thanks,
Sven

On Apr 26, 2015, at 1:50 PM, "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov> wrote:

Sven – Attached is a one page document that encompasses all of the articles language. I wanted to share it with you all to make sure this was all consistent with what you had previously sent over. Hoping this all works with no edits on our end but we may have to come back with a request for TA on a minor change or two.

Thanks as always for the help!

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Saturday, April 25, 2015 5:56 PM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW)
Subject: Udall Inhofe TSCA TA on Articles

Jonathan and Dimitri,
This follows up on your earlier request on articles. Attached please find the requested technical assistance. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily

represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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<Articles.docx>
<Articles comment.docx>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/10/2015 1:43:59 PM
To: Zipkin, Adam (Booker) [Adam_Zipkin@booker.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Re: SEPW TSCA TA

Checking

On Jul 10, 2015, at 9:33 AM, "Zipkin, Adam (Booker)" <Adam_Zipkin@booker.senate.gov> wrote:

Sven so that I am clear – on #3 regarding small manufacturers, are you saying that in 2011 EPA considered updating/revising the 1984 definition and decided that no change was warranted? Was SBA consulted?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, July 02, 2015 9:29 AM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW); Zipkin, Adam (Booker); Deveny, Adrian (Merkley)
Subject: SEPW TSCA TA

Jonathan,
This technical assistance responds to several requests. The language on small manufacturers is in addition to earlier TA on the same subject. The technical assistance is intended for use only by the requesters. The technical assistance does not necessarily repr3esent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

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1. Regarding the "denominator issue":

The following suggested redrafting is intended to effectuate what we understand to be the policy objective behind section 4A(c)(2)(A) without suggesting, as the current draft does, that "additional priorities" designated under 4A(c)(1) are a subset of high priority chemicals designated under subsections 4A(a)(2) or (b)(3). Our understanding of the policy objective is that, in calculating the number of additional priority chemicals, the denominator for the required 25%-30% range should be the number of high-priority chemicals designated under those subsections, not the total number of chemicals designated to undergo safety assessments and safety determinations. Redline is from the version voted out of Committee:

> Sec 4A(c)(2)(A) – if a sufficient number of additional priority requests meet the requirements of paragraph (1), **the number of substances designated to undergo safety assessments and safety determinations under the process and criteria pursuant to paragraph (1) shall be** not less than 25 percent, or more than 30 percent, of the cumulative number of substances designated to undergo safety assessments and determinations under **subsections (a)(2) and (b)(3).** ~~this section are substances designated under the process and criteria pursuant to paragraph (1).~~

2. Regarding imports:

- ? <!--[if !supportLists]--><!--[endif]-->Following is the new text that you requested, addressing existing chemical substances that were added to the TSCA inventory, after a Section 5 determination that they were not likely to meet the safety standard. Such a determination would trigger restriction under 5(d)(4), which would be part of the basis for a new exception to the export exemption.
- ? <!--[if !supportLists]--><!--[endif]-->This resolves the technical concern about an exported new chemical substance being made subject to TSCA under (A) and then ceasing to be subject to TSCA as soon as the chemical substance becomes an existing chemical subject to a section 5 order. Once the chemical is added to the Inventory, it would remain excepted from the export exemption, but now under (C) rather than under (A).
- ? <!--[if !supportLists]--><!--[endif]-->This also provides that if domestic uses of a new chemical substance are restricted under a section 5 order, it would only take a "likely to present" finding, with respect to the exported volumes, to later make the exported volumes of such chemical substance subject to TSCA jurisdiction.

"(2) EXCEPTION.—Paragraph (1) shall not apply to—

"(A) any new chemical substance that the Administrator determines is likely to present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors; ~~or~~
"(B) any chemical substance that the Administrator determines presents or will present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors; **or**
"(C) any chemical substance that:

(i) <!--[if !supportLists]--><!--[endif]-->**the Administrator determines is likely to present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors; and**

(ii) <!--[if !supportLists]--><!--[endif]-->**is subject to restriction under section 5(d)(4)**

3. Regarding small manufacturers:

- ? <!--[if !supportLists]--><!--[endif]-->For purposes of Chemical Data Reporting, the operative definition of "small manufacturer or importer" is found at 40 CFR 704.3. Chemical manufacturers that fall under this definition are generally exempt from reporting. 40 CFR 711.9. The standard used in the definition of "small manufacturer or importer" was established in 1984. 49 FR 45425. In 2011, EPA analyzed potential small business impacts of Chemical Data Reporting using both the SBA employee size standards and the TSCA sales-based definition of small business. 76 FR 50858.

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, June 29, 2015 2:06 PM
To: Kaiser, Sven-Erik; Karakitsos, Dimitri (EPW); Zipkin, Adam (Booker); Deveny, Adrian (Merkley)
Subject: RE: SEPW TSCA TA

Thanks! I'm glad someone is keeping track!

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, June 29, 2015 2:05 PM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW); Zipkin, Adam (Booker); Deveny, Adrian (Merkley)
Subject: SEPW TSCA TA

Jonathan,
I think there are 3 outstanding TA requests below. The first two are underway and included is the response to the small manufacturers definition question. Please let me know if any additional questions. Thanks,
Sven

– exports (EPA working on TA)

– cap on industry assessments (EPA to provide text change on p.22, line 18)

– small manufacturers definition

EPA response: most of EPA's TSCA programs, including CDR, use the same definition for small business as defined by regulation in 40 CFR 704.3. This definition has never been updated. A few TSCA programs use different definitions of small business, including for 8(a) PAIR and for calculating PMN fees.

Small manufacturer or importer means a manufacturer or importer that meets either of the following standards:

(1) *First standard.* A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $40 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer or importer is greater than 45,400 kilograms (100,000 pounds), the manufacturer or importer shall not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer or importer qualifies as small under standard (2) of this definition.

(2) *Second standard.* A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $4 million, regardless of the quantity of substances produced or imported by that manufacturer or importer.

(3) Inflation index. EPA shall make use of the Producer Price Index for Chemicals and Allied Products, as compiled by the U.S. Bureau of Labor Statistics, for purposes of determining the need to adjust the total annual sales values and for determining new sales values when adjustments are made. EPA may adjust the total annual sales values whenever the Agency deems it necessary to do so, provided that the Producer Price Index for Chemicals and Allied Products has changed more than 20 percent since either the most recent previous change in sales values or the date of promulgation of this rule, whichever is later. EPA shall provide Federal Register notification when changing the total annual sales values.

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From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, June 29, 2015 1:37 PM
To: Kaiser, Sven-Erik
Cc: Karakitsos, Dimitri (EPW); Zipkin, Adam (Booker); Deveny, Adrian (Merkley)
Subject: Follow-up

Hey Sven, sorry again to miss the call last week. My understanding was there might be one more follow-up on exports? Are we waiting for anything from EPA?

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/20/2015 9:31:10 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on CBI
Attachments: Markey.TSCA TA.CBI.docx

Michal,
This responds to the technical assistance request on TSCA CBI provisions in S.697. The attached technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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Washington, DC 20460
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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, May 14, 2015 6:46 PM
To: Kaiser, Sven-Erik
Cc: Freedhoff, Michal (Markey)
Subject: another TSCA TA request

This one is related to the CBI provisions that require EPA to review CBI claims for active substances that have been in place for longer than 5 years.

How many CBI claims are currently in place for active substances that have been there for more than 5 years?
How many CBI claims are in place for inactive substances?

The bill gives EPA a 5 year deadline to re-review CBI claims for active substances, and encourages manufacturers of inactive substances to voluntarily withdraw them. We have received a proposal that the deadline for active substances be changed to 3 years, and a deadline for inactive substances of 1 year be imposed.

We suspect that there could be resource/budget concerns here that we would like to understand, so would like to know whether the proposal we received is feasible, what it would take to accomplish, etc.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
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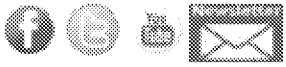
Connect with Senator Markey



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Q. How many CBI claims are currently in place for active substances that have been there for more than 5 years?

A. While there are a number of new obligations for EPA to review CBI under the bill, these responses assume the question is referring to section 8(b)(4)(C) (p. 93) which requires EPA to "promulgate a rule that establishes a plan to review all claims to protect the specific identities of chemical substances on the confidential portion of the" list of active substances. Section 8(b)(4)(E) (p. 96) requires EPA to review these claims within 5 years after EPA "compiles the initial list of active substances" under (b)(4)(A). The other 5 year cutoff relating to these provisions is whether a company has to resubstantiate their CBI claim for chemical identity at the time they are reporting the chemical as active or whether they can rely on a substantiation that was provided in a submission within the prior 5 years (section 8(b)(4)(D)(i)). With these interpretations in mind, these responses reflect the number of chemical substances on the TSCA inventory with specific chemical identity claimed as confidential, but does not include any information about CBI claims for other data elements or in other types of submissions to EPA. If these assumptions are incorrect, please let us know what other information is required.

The Agency does not currently collect or track information indicating whether chemicals on the TSCA inventory are "active" versus "inactive". These responses are based on educated, but speculative calculations.

- The TSCA Inventory is made up of chemicals that are permitted to be legally used in US commerce. Of the approximate 85,000 chemicals on the TSCA Inventory, about 17,500 are listed on the confidential portion of the Inventory - or about 20%.

- A subset of the TSCA Inventory, about 7,600 substances, were reported in the Chemical Data Reporting (CDR) data collection in 2012. The Chemical Data Reporting rule requires manufacturers and importers to provide the Agency with information on the production and use of chemicals in commerce in large quantities. This is a subset of the likely universe of "active" chemicals because of exemptions based on chemical type, site reported production volume and other exemptions.

- Of the 7,600 chemicals reported in the Chemical Data Reporting (CDR) collection, 231 were claimed as confidential. But confidential chemicals are likely disproportionately exempt from CDR reporting because they frequently have very specialized purposes and do not meet CDR production volume thresholds.

- About 400 chemicals are added to the TSCA Inventory each year—of which about half have specific chemical identity treated as CBI. Presumably these 400 are "active." Some have speculated that there may be as many as 25,000 chemicals on the Inventory which are "active," meaning actually in commerce, in some volume, over the last 5 years, and possibly as many as 20% of these chemicals, 5,000, being treated as CBI.

Q. How many CBI claims are in place for inactive substances?

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A. Working backwards from the speculative estimate explained above, if there about 17,500 chemicals on the confidential portion of the TSCA inventory and approximately 5,000 are "active", then the remaining approximately 12,500 chemicals from the confidential portion of the TSCA inventory would be inactive.

Q. The bill gives EPA a 5 year deadline to re-review CBI claims for active substances, and encourages manufacturers of inactive substances to voluntarily withdraw them. We have received a proposal that the deadline for active substances be changed to 3 years, and a deadline for inactive substances of 1 year be imposed.

A. Given the substantiation requirements that EPA is required to impose as an element of the reporting process for active substances, any CBI claims for active substances resulting from the reporting process EPA are likely to be ones which the submitter strongly feels should remain as CBI. Assuming submitters provide the required substantiations, it would be likely that most of these claims would be approved and the 3 year deadline, while aggressive, is potentially attainable.

It is much more difficult to speculate as to how easily CBI claims for inactive substances might be to review and approve, modify, or deny as the bill requires for active chemicals. It seems unlikely that companies would voluntarily submit withdrawals of CBI claims for inactive chemicals without prompting from EPA. Initiating this type of prompting would require a significant amount of EPA resources, particularly if the rough estimate of 12,500 inactive CBI chemicals above is accurate. For these reasons the 1 year deadline for inactive claims does not seem practicable.

Q. We suspect that there could be resource/budget concerns here that we would like to understand, so would like to know whether the proposal we received is feasible, what it would take to accomplish, etc.

A. From an EPA perspective, the bill imposes a number of other new obligations with respect to reviewing CBI claims which would be occurring concurrently with these requirements. For example, EPA would be required to review and act on ALL new CBI claims for chemical identity under 14(g)(1) within 90 days of receipt, and review and act on a 25% representative subset of all other CBI claims under 14(g)(1), within 90 days of receipt.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/10/2015 1:43:40 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Hunt, Jasmine (Durbin) [Jasmine_Hunt@durbin.senate.gov]; Joseph, Avenel (Markey) [Avenel_Joseph@markey.senate.gov]
Subject: Re: Senate TSCA TA on State Preemption and Science

Got it, will provide a response. Thanks,
Sven

On Jul 10, 2015, at 9:19 AM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Thank you

No intentional removal of the "based on the judgement" language, was just sending the replacement portion of the provision.

I'm not certain your version works exactly. Intent was to tie the science finding to the "risk" and have a requirement that the state action is designed to meet the risk but not be tied to the same science finding. Do you think this quickly drafted alternative could work?

YOURS:

"In the judgment of the Administrator, the statute or administrative action of the state or political subdivision of the state is designed to address a risk of a chemical substance under the conditions of use and is the product of decision-making that is of a quality comparable to that specified under section 3A(c)(3)(A)."

ALTERNATIVE:

"In the judgment of the Administrator, the statute or administrative action of the state or political subdivision of the state, is designed to address a risk of a chemical substance under the conditions of use that was identified using decision-making that is of a quality comparable to that specified under section 3A(c)(3)(A)."

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Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, July 10, 2015 7:46 AM
To: Freedhoff, Michal (Markey)
Cc: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW); Hunt, Jasmine (Durbin)
Subject: Senate TSCA TA on State Preemption and Science

Michal,
This responds to your TA request.

Was the deletion of the phrase "based on the judgment of the Administrator" intentional? The presence or absence of this phrase affects the degree of discretion that EPA would have in making decisions on these waivers.

3(A)(c)(3)(A) is not itself a description of a particular kind of information. It is a directive to ensure that policies, procedures, and guidance ensure that EPA engages in a particular kind of decision-making. The decision-making rubric includes factors other than the quality of the information upon which the decision was made (e.g, whether EPA properly weighted and analyzed the information)

A potentially clearer way of expressing your intentions:

"[In the judgment of the Administrator], the statute or administrative action of the state or political subdivision of the state is designed to address a risk of a chemical substance under the conditions of use and is the product of decision-making that is of a quality comparable to that specified under section 3(A)(c)(3)(A)."

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

On Jul 9, 2015, at 1:09 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

We will also need some TA on the language below, which is a potential alternative to the science prong on the section 18a waiver. Basically trying to say "the science about the risk is solid, and the state requirement is designed to address that risk".

The statute or administrative action of the state or political subdivision of the state is designed to address a risk of a chemical substance under the conditions of use that is based on information that is consistent with section 3(A)(c)(3)(A)

From: Kaiser, Sven-Erik
Sent: Thursday, July 9, 2015 12:03 PM
To: Black, Jonathan (Tom Udall)
Cc: Karakitsos, Dimitri (EPW); Freedhoff, Michal (Markey); Hunt, Jasmine (Durbin)
Subject: Re: Senate TSCA TA Call on Fees and Budget

Yes- 1pm- call 866-299-3188, code 202-566-2753#. Thanks,
Sven

On Jul 9, 2015, at 11:45 AM, "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov> wrote:

Our plan is to call at 1.

From: Kaiser, Sven-Erik
Sent: Wednesday, July 8, 2015 5:35 PM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW); Freedhoff, Michal (Markey); Hunt, Jasmine (Durbin)
Subject: Senate TSCA TA Call on Fees and Budget

Jonathan,
I'm getting folks together, let's say tentatively a call tomorrow, Thurs, July 9 at 1pm. Let me know if the time moves. Please call 866-299-3188, code 202-566-2753#. Thanks,
Sven

Sven-Erik Kaiser
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Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Wednesday, July 08, 2015 4:01 PM
To: Kaiser, Sven-Erik
Cc: Karakitsos, Dimitri (EPW); Freedhoff, Michal (Markey); Hunt, Jasmine (Durbin); Black, Jonathan (Tom Udall)
Subject: EPA T.A. Call on TSCA Fees and Budget

Sven, we are meeting from 1130-2pm tomorrow. One of the topics of discussion will be TSCA fees and the budget, specifically, how to key the minimum appropriations to ensure that EPA can set user fees.

We'd like to know how OMB A11 intersects with the budgeting and what is covered in the TSCA office.

Our preference is to call in around 1pm if possible. We'd also like to include Dem and GOP Senate Appropriations staff.

Others can chime in about the things they'd like to ask about.

Thanks,
---Jonathan

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/26/2015 9:19:56 PM
To: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
Subject: Re: Udall Inhofe TSCA TA on Articles

Checking

On Apr 26, 2015, at 5:19 PM, "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov> wrote:

Are folks available for a quick call at 5:30?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Sunday, April 26, 2015 04:43 PM
To: Karakitsos, Dimitri (EPW)
Cc: Black, Jonathan (Tom Udall)
Subject: Re: Udall Inhofe TSCA TA on Articles

Dimitri,
In response to your request, the consolidated language you sent over in your first email is fine, with one exception: in the section 5 language, the word "potential" should be inserted between "identified" and "risks". In PMN review, EPA identifies and reacts to potential risk; it does not do a full risk assessment and identify known risks. We had intended to include "potential" in our earlier email to you but apparently didn't do so -- sorry.

Re Richard Dennison's comments: We do not agree with his suggested changes to the SNUR language, for two reasons.

First, rather than requiring EPA to make an "affirmative finding" that the potential for exposure through articles warrants notification as our TA language did, Dennison's language would require EPA to "demonstrate" the potential for exposure through articles. We see that as a higher bar.

Second, as we interpret section 5(a), it automatically applies to chemicals in articles, for both SNUNs and PMNs, unless we exempt them. His drafting suggests otherwise and may be read to narrow the scope of section 5(a).

Some of his concerns in this regard are focused on the final sentence in our TA -- ie, **Nothing in this paragraph shall be construed to limit the Administrator's authority to exempt the import or processing of a chemical substance from requirements under 5(a)(1)(A).** Although we see some potential value to this sentence, it's not essential from our perspective and we don't see it as worth arguing over; so it could just be dropped.

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser
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On Apr 26, 2015, at 2:31 PM, "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov> wrote:

Before you get to far – Richard already raised some significant concerns on his end and I have attached a draft with his edits to the SNUR language.

I think it best at this point if you could please help with 2 things. First make sure our other provisions for Sections 5 and 6 are consistent with TA and second can we set up a call to discuss the overall language and the SNUR language with Richard and Mark Greenwood for some time this afternoon?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Sunday, April 26, 2015 1:54 PM
To: Karakitsos, Dimitri (EPW)
Cc: Black, Jonathan (Tom Udall)
Subject: Re: Udall Inhofe TSCA TA on Articles

Dimitri,
Got it- forwarding to folks. Thanks,
Sven

On Apr 26, 2015, at 1:50 PM, "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov> wrote:

Sven – Attached is a one page document that encompasses all of the articles language. I wanted to share it with you all to make sure this was all consistent with what you had previously sent over. Hoping this all works with no edits on our end but we may have to come back with a request for TA on a minor change or two.

Thanks as always for the help!

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Saturday, April 25, 2015 5:56 PM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW)
Subject: Udall Inhofe TSCA TA on Articles

Jonathan and Dimitri,
This follows up on your earlier request on articles. Attached please find the requested technical assistance. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

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202-566-2753

<Articles.docx>
<Articles comment.docx>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/18/2015 12:55:57 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: Sen. Udall TSCA TA Inquiry on Disease Clusters

Jonathan,
Thank you for the question about EPA's role in disease cluster research and grants. Generally, EPA has not been the lead on disease clusters -- typically CDC/ATSDR undertakes any epidemiological studies or related activities. At some of our Superfund sites we provide community advisory groups with technical assistance funding to help them hire an advisor to address site related technical documents generated by EPA or responsible parties and that can include getting a better understanding of site related health risk or review of health related data. EPA does support some long term epidemiological research done through research grants to academic institutions that may include some that look at reported disease clusters. But, to our knowledge, we have not provided grants to academic institutions or nonprofits to investigate potential disease clusters. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Thursday, May 14, 2015 11:19 AM
To: Kaiser, Sven-Erik
Subject: S.50 | 113th Congress

Hi Sven, this was filed as an amendment to S.697 in April.

Does EPA have any experience working with this type of grant making?

S.50

Strengthening Protections for Children and Communities From Disease Clusters Act (Introduced in Senate - IS)

S 50 IS

113th CONGRESS
1st Session
S. 50

To direct the Administrator of the Environmental Protection Agency to investigate and address cancer and disease clusters, including in infants and children.

IN THE SENATE OF THE UNITED STATES

January 22 (legislative day, January 3), 2013

Mrs. BOXER (for herself and Mr. CRAPO) introduced the following bill; which was read twice and referred to the Committee on Environment and Public Works

---

A BILL

To direct the Administrator of the Environmental Protection Agency to investigate and address cancer and disease clusters, including in infants and children.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the `Strengthening Protections for Children and Communities From Disease Clusters Act'.

SEC. 2. FINDINGS.

Congress finds that--

(1) children are particularly at risk from environmental pollutants or toxic substances for various reasons, including because--

(A) the nervous, immune, digestive, and other systems of children are still developing as the children move though several stages of rapid growth and development;

(B) exposure to environmental pollutants or toxic substances can affect prenatal, infant, and childhood growth and development;

(C) children may be less able to detoxify and excrete toxins than adults;

(D) children eat proportionately more food, drink more fluids, breathe more air, and play outside more, which means children are more exposed to environmental pollutants and toxic substances than adults;

(E) children are less able to protect themselves from exposures to environmental pollutants or toxic substances;

(F) the behavior of children exposes children to different environmental pollutants and toxic substances than adults;

(G) the natural curiosity and tendency of children to explore leaves children open to health risks that adults can more easily avoid; and

(H) the developing brains, reproductive systems, and other organs of children are more susceptible to permanent disruption that can result in health problems during the lives of the children;

(2) according to the Department of Health and Human Services, birth defects are the leading cause of infant death in the first year of life, accounting for about 20 percent of infant deaths in 2006;

(3) according to the American Cancer Society, cancer is the second leading cause of death in children, exceeded only by accidents;

(4) according to the Centers for Disease Control and Prevention, an estimated 1 in 110 children in the United States have an autism spectrum disorder;

(5) scientific research on environmental, genetic, and other influences that may affect environmental health is a national priority;

(6) Federal agencies should work to address serious environmental health problems to better protect children and other individuals in communities, both large and small, across the United States; and

(7) according to the National Academy of Sciences--

(A) it is in the national interest to place a higher priority on the health of children;

(B) in the short term, that priority will result in children whose health and quality of life is improved and who are more ready and able to learn;

(C) children have important value in their own right and are worthy of that type of societal commitment;

(D) it is also in the national interest to optimize the health of children because, in the long term--

(i) the continuing viability of society depends on a citizenry and a workforce that are properly equipped to be productive and committed to serving the country; and

(ii) failure to improve the health of children will have a substantial long-term consequence for the health of the adult population; and

(E) investing in the health of children is necessary for all of the reasons described in subparagraphs (A) through (D) and is the right thing to do.

SEC. 3. PURPOSES.

The purposes of this Act are--

(1) to provide to the Administrator the authority to help conduct investigations into the potential for environmental pollutants or toxic substances to cause disease clusters;

(2) to ensure that the Administrator has the authority to undertake actions to help address existing and potential environmental pollution and toxic substances that may contribute to the creation of disease clusters; and

(3) to enable the Administrator to integrate and work in conjunction with other Federal, State, and local agencies, institutions of higher education, and the public in investigating and helping to address the possible causes of disease clusters.

SEC. 4. GOALS.

The goals of this Act are--

(1) to protect and assist pregnant women, infants, children, and other individuals who have been, are, or could be harmed by, and become part of, a disease cluster;

(2) to enhance Federal resources, expertise, outreach, transparency, and accountability in responding to public and State and local government inquiries about the potential causes of a disease cluster;

(3) to strengthen Federal analytical capacity and coordination, including with State and local authorities, in the investigation of the potential causes of disease clusters;

(4) to develop multidisciplinary teams that undertake a systematic, integrated approach to investigate and help address the potential causes of disease clusters that State and local officials cannot address or need assistance in addressing; and

(5) to help facilitate the rapid investigation of potential disease clusters and actions to address the potential causes of disease clusters.

SEC. 5. DEFINITIONS.

In this Act:

(1) ADMINISTRATOR- The term `Administrator' means the Administrator of the Environmental Protection Agency.

(2) AGENCY- The term `Agency' means the Environmental Protection Agency.
(3) DIRECTOR- The term `Director' means the Director of the National Institute of Environmental Health Sciences.
(4) DISEASE CLUSTER- The term `disease cluster' means--

(A) the occurrence of a greater-than-expected number of cases of a particular disease within a group of individuals, a geographical area, or a period of time; or

(B) the occurrence of a particular disease in such number of cases, or meeting such other criteria, as the Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry and the Director, may determine.

(5) ENVIRONMENTAL POLLUTANTS OR TOXIC SUBSTANCES- The term `environmental pollutants or toxic substances' includes the substances described in paragraph (7).
(6) FEDERAL AGENCY- The term `Federal agency' means--

(A) any department, agency, or other instrumentality of the Federal Government;

(B) any independent agency or establishment of the Federal Government (including any Government corporation); and

(C) the Government Printing Office.

(7) POTENTIAL CAUSES OF A DISEASE CLUSTER- The term `potential causes of a disease cluster' includes environmental and public health factors that could increase the possibility of disease clusters, including environmental pollutants or toxic substances and sources of those pollutants and substances, including--

(A) emissions of air pollutants that are regulated under the Clean Air Act (42 U.S.C. 7401 et seq.);

(B) water pollutants that are regulated under the Federal Water Pollution Control Act (33 U.S.C. 1251 et seq.);

(C) a contaminant, as that term is defined in section 1401 of the Safe Drinking Water Act (42 U.S.C. 300f);

(D) a hazardous substance, as that term is defined in section 101 of the Comprehensive Environmental Response, Compensation, and Liability Act (42 U.S.C. 9601);

(E) solid waste and hazardous waste, as those terms are defined in section 1004 of the Solid Waste Disposal Act (42 U.S.C. 6903);

(F) a chemical substance, as that term is defined in section 3 of the Toxic Substances Control Act (15 U.S.C. 2602);

(G) a substance that is regulated under the Emergency Planning and Community Right-To-Know Act of 1986 (42 U.S.C. 11001 et seq.); and

(H) any other form of environmental pollution or toxic substance that is a known or potential cause of an adverse health effect, including a developmental, reproductive, neurotoxic, or carcinogenic effect.

(8) REGIONAL RESPONSE CENTER- The term `Regional Response Center' means a Regional Disease Cluster Information and Response Center established under section 7.
(9) RESPONSE TEAM- The term `Response Team' means a Regional Disease Cluster Information and Response Team established under section 7.
(10) SECRETARY- The term `Secretary' means the Secretary of Health and Human Services.

SEC. 6. GUIDELINES FOR ENVIRONMENTAL INVESTIGATIONS OF DISEASE CLUSTERS.

(a) Establishment-

(1) IN GENERAL- The Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry, the Secretary, and the Director, shall develop, publish, and periodically update guidelines that describe a systematic, integrated approach that uses the best available science to investigate--

(A) 1 or more suspected or potential disease clusters;
(B) environmental pollutants or toxic substances associated with 1 or more suspected or potential disease clusters; or
(C) potential causes of 1 or more disease clusters.

(2) COORDINATION- The Administrator shall ensure that the Office of Children's Health Protection, in consultation with appropriate advisory committees, such as the Children's Health Protection Advisory Committee, has a prominent role on behalf of the Agency in developing and updating guidelines under paragraph (1).

(b) Requirements- Guidelines developed under this section shall include--
(1) definitions of key concepts and actions;
(2) disease cluster identification and reporting protocols;
(3) standardized methods of reviewing and categorizing data, including from health surveillance systems and disease cluster reports;
(4) guidance for using, in a health-protective way, an appropriate epidemiological, statistical, or other approach for the circumstances of an investigation;
(5) procedures for peer review of key documents by individuals who have no direct or indirect conflict of interest; and
(6) a description of roles and responsibilities of the Administrator and the Administrator of the Agency for Toxic Substances and Disease Registry in conducting investigations described in those guidelines, in accordance with this Act.

(c) Timing-
(1) IN GENERAL- Draft guidelines developed under this section shall be available for public review and comment for a period of not less than 60 days.
(2) FINAL GUIDELINES- Not later than 1 year after the date of enactment of this Act, the Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry, the Secretary, and the Director, shall publish in the Federal Register final guidelines under this section.

SEC. 7. ENHANCED SUPPORT FOR ENVIRONMENTAL INVESTIGATIONS OF DISEASE CLUSTERS.

(a) Establishment of Regional Disease Cluster Information and Response Centers and Teams-
(1) ESTABLISHMENT-
(A) IN GENERAL- The Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry, the Secretary, and the Director, and other appropriate Federal agencies, shall establish and operate Regional Disease Cluster Information and Response Centers and Regional Disease Cluster Information and Response Teams.
(B) PRINCIPAL RESPONSIBILITY- The Administrator shall be principally responsible for directing, coordinating, and approving Federal efforts and assistance authorized under this section.
(2) COORDINATION-
(A) IN GENERAL- The Administrator shall ensure that the Office of Children's Health Protection, in consultation with appropriate advisory committees, such as the Children's Health Protection Advisory Committee, has a prominent role on behalf of the Agency in establishing and operating the Regional Response Centers and the Response Teams.
(B) GRANTS AND COOPERATIVE AGREEMENTS-
(i) IN GENERAL- The Administrator shall provide support (including research, program implementation, and operational support activities) to individuals on Response Teams described in subsection (b) and Community Disease Cluster Advisory Committees described in subsection (c) through grants and cooperative

agreements with institutions of higher education that have programs or individuals with demonstrated expertise in research, training, studies, and technical assistance.

(ii) AUTHORIZATION OF APPROPRIATIONS- There are authorized to be appropriated to carry out this subparagraph such sums as are necessary.

(3) TIMING- Not later than 1 year after the date of enactment of this Act, the Administrator shall establish at least--

(A) 2 Regional Response Centers; and

(B) 2 Response Teams.

(b) Response Teams-

(1) MEMBERSHIP- Each Response Team shall include individuals who--

(A) have expertise in epidemiology, toxicogenomics, molecular biology, toxicology, pollution control requirements, data analysis, environmental health and disease surveillance, exposure assessment, pediatric health, community outreach and involvement, and other relevant fields; and

(B) have no direct or indirect conflict of interest.

(2) LEADERSHIP- Each Response Team shall have--

(A) an individual who is the leader of the Response Team and who reports to the Administrator, the Administrator of the Agency for Toxic Substances and Disease Registry, and the Director; and

(B) an individual who has the skills or experience necessary to carry out community outreach and involvement activities, including--

(i) the establishment of Community Disease Cluster Advisory Committees under subsection (c); and

(ii) the facilitation of activities of those Committees.

(3) ACTIVITIES-

(A) IN GENERAL- The Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry and the Director, shall establish the scope of activities for Response Teams to ensure that the activities are consistent with achieving the goals of this Act.

(B) REQUIREMENTS- The activities of the Response Teams shall include--

(i) making guidelines, protocols, data, and other relevant information and expertise available to State and local officials and the public to assist in efforts--

(I) to investigate suspected or potential disease clusters, environmental pollutants or toxic substances associated with those disease clusters, and potential causes of disease clusters; and

(II) to address potential causes of disease clusters;

(ii) responding rapidly to a petition described in subparagraph (C) from any person, including a State or local official, regarding the need--

(I) to investigate suspected or potential disease clusters, environmental pollutants or toxic substances associated with those disease clusters, and potential causes of disease clusters; and

(II) to address the potential causes of disease clusters;

(iii) providing the best available environmental sampling and laboratory equipment to collect, analyze, and interpret monitoring, health surveillance, and other relevant information at scales and timelines appropriate to an action;

(iv) involving community members, in accordance with established scientific methods and norms (including the preservation of the confidentiality of individuals), in--

(I) investigations of suspected or potential disease clusters, environmental pollutants or toxic substances associated with those disease clusters, or potential causes of disease clusters, including through--

(aa) environmental exposure assessments;

(bb) biomonitoring activities; and

(cc) community-based participatory research initiatives; and

(II) other efforts to address the potential causes of disease clusters;

(v) working with State and local agencies--

(I) to help make the use and management of integrated environmental health data consistent and timely; and

(II) to fill data gaps; and

(vi) investigating suspected or potential disease clusters, environmental pollutants or toxic substances associated with those disease clusters, and potential causes of disease clusters, and addressing the potential causes of disease clusters that the Administrator determines State and local officials need assistance in investigating or addressing, or that the Administrator determines should be investigated or addressed.

(C) PETITION-

(i) IN GENERAL- Any person, including a State or local official, may submit a petition referred to in subparagraph (B)(ii) to the Administrator, the Administrator of the Agency for Toxic Substances and Disease Registry, and the Director that requests that a Response Team conduct an investigation or take other action to address the potential causes of disease clusters in accordance with this Act.

(ii) REQUIREMENTS- Each petition submitted under clause (i) shall clearly describe the basis for the requested investigation or action, including any data supporting the request.

(iii) CONSIDERATION- The Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry and the Director, shall establish criteria for the consideration of petitions submitted under this section using health-protective factors, including--

(I) evidence of the release of environmental pollutants or toxic substances;

(II) the locations in which there appear to be potentially significant health threats from the potential causes of disease clusters;

(III) cases in which existing data appear to be inadequate to fully assess the potential risks to public health; and

(IV) such other factors as the Administrator determines are necessary.

(iv) RESPONSE- Not later than 60 days after the date of receipt of a petition under clause (iii), the Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry and the Director, shall provide a written response that describes--

(I) the investigation or actions that will be undertaken in response to the petition, including the timeline and basis for the investigation or actions; and

(II) the reasons for any denial or deferral in providing such a response.

(v) TIMING OF ISSUANCE OF CRITERIA-

(I) IN GENERAL- The Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry and the Director, shall provide for public notice of draft criteria established under this subparagraph for a period of not less than 60 days.

(II) FINAL CRITERIA- Not later than 1 year after the date of enactment of this Act, the Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry and the Director,

shall publish in the Federal Register final criteria required under this subparagraph.

(4) USE OF PUBLICLY AVAILABLE REPORTS- Response Team investigations and actions shall--

(A) include publicly available reports prepared by the Response Team that contain statements of facts, findings, and recommendations for actions, to the extent appropriate; and

(B) be prepared in a manner that preserves the confidentiality of individuals.

(5) TRANSPARENCY AND ACCOUNTABILITY- Response Team activities shall include measures to ensure--

(A) transparency and accountability to potentially affected individuals, State and local officials, the public, and other persons and agencies, while preserving the confidentiality of individuals;

(B) that consistent, accurate, and meaningful information is provided to potentially affected individuals, State and local officials, the public, and other persons and agencies through the use of comprehensive, community-based communications plans; and

(C) accountability to meeting goals and timetables.

(6) DATABASE-

(A) IN GENERAL- The Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry, the Secretary, and the Director, shall compile and regularly update information in a comprehensive electronic database that--

(i) is publicly accessible through the Internet;

(ii) provides a centralized location for information relating to--

(I) disease cluster reports and investigations;

(II) environmental pollutants or toxic substances that are associated with suspected or potential disease clusters;

(III) illnesses associated with suspected or potential disease clusters, including locally generated information;

(IV) systematic tracking of environmental pollutants or toxic substances and illnesses associated with suspected or potential disease clusters;

(V) actions to help address the potential causes of disease clusters; and

(VI) any other information that the Administrator determines to be necessary; and

(iii) facilitates the rapid reporting and analysis of information described in clause (ii).

(B) CONFIDENTIALITY- A database described in subparagraph (A) shall be maintained in a manner that preserves the confidentiality of individuals.

(c) Community Disease Cluster Advisory Committees-

(1) IN GENERAL- The Administrator shall establish Community Disease Cluster Advisory Committees to provide oversight, guidance, and advice relating to--

(A) the investigation of suspected and potential disease clusters;

(B) the investigation of environmental pollutants or toxic substances associated with suspected or potential disease clusters;

(C) the investigation of potential causes of disease clusters;

(D) efforts to address the potential causes of disease clusters; and

(E) the most effective means of ensuring outreach to and involvement of community members.

(2) MEMBERSHIP- Membership on Community Disease Cluster Advisory Committees shall be comprised of representatives that include--

(A) individuals who are or may be impacted by a suspected or potential disease cluster, and the designee of such an individual who may participate with or in the place of such an individual;

(B) State or local government health or environmental agencies;
(C) at least 2 individuals, appointed by the Administrator in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry and the Director, with demonstrated knowledge of the activities described in paragraph (1); and
(D) other appropriate individuals, as determined by the Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry and the Director.

(3) PROHIBITION- No member of a Committee may have any direct or indirect conflict of interest.

(4) TECHNICAL ASSISTANCE-

(A) IN GENERAL- The Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry and the Director, may make grants available to any group of individuals that may be affected by a suspected or potential disease cluster.

(B) USE OF FUNDS- Grants made available under subparagraph (A) may be used to facilitate active involvement in all aspects of Committee activities and to assist Committee members in obtaining technical assistance in interpreting information with regard to--

(i) the investigation of--

(I) suspected or potential disease clusters;
(II) environmental pollutants or toxic substances that are associated with suspected or potential disease clusters; and
(III) the potential causes of disease clusters;

(ii) addressing the potential causes of disease clusters;
(iii) understanding the health concerns associated with suspected or potential disease clusters; and
(iv) understanding other scientific and technical issues relating to the activities of a Regional Response Team and Community Disease Cluster Advisory Committee, including the potential need for and interpretation of any biomonitoring of individuals in the area.

(d) Environmental Research and Analysis- The Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry, the Secretary, and the Director, shall use available authorities and programs to compile, research, and analyze information generated by actions authorized under this section, including by--

(1) using those authorities to test environmental pollutants or toxic substances identified under subsection (b)(6); and
(2) incorporating environmental pollutants or toxic substances identified under subsection (b)(6) in appropriate national biomonitoring initiatives.

SEC. 8. FEDERAL REPORTS TO CONGRESS.

(a) In General- Not later than 1 year after the date of enactment of this Act and annually thereafter, the Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry, the Secretary, and the Director, shall prepare a report that describes--

(1) the status of activities under this Act to investigate and address the suspected and potential causes of disease clusters;
(2) environmental pollutants or toxic substances that are associated with suspected or potential disease clusters;
(3) the potential causes of disease clusters; and
(4) ways to address the potential causes of those disease clusters.

(b) Requirements- The report shall include a description of--

(1) outreach activities to State and local officials and communities;

(2) actions that the Administrator has taken to prioritize the testing of environmental pollutants or toxic substances;
(3) actions that the Administrator has taken to include environmental pollutants or toxic substances identified under section 7(b)(7) in appropriate national biomonitoring initiatives;
(4) actions that the Administrator is taking or plans to take to address problems in implementing this Act;
(5) actions that the Secretary is taking or plans to take to address problems in implementing this Act;
(6) actions that the Administrator of the Agency for Toxic Substances and Disease Registry has undertaken or is considering taking with respect to any disease clusters under subparagraphs (D) and (E) of section 104(i)(1) of Comprehensive Environmental Response, Compensation, and Liability Act (42 U.S.C. 9604(i)(1)) and other provisions of that section;
(7) actions that the Director is taking or plans to take to address problems in implementing this Act; and
(8) other relevant information.

(c) Submission and Availability- The Administrator shall--
(1) submit the report under this subsection to--
(A) the Committees on Environment and Public Works and Health, Education, Labor, and Pensions of the Senate; and
(B) the Committee on Energy and Commerce of the House of Representatives; and
(2) make the report available to the public.

SEC. 9. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated such sums as are necessary to carry out this Act.

SEC. 10. EFFECT ON OTHER LAW.

Nothing in this Act modifies, limits, or otherwise affects the application of, or obligation to comply with, any law, including any environmental or public health law.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/9/2015 5:51:45 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Hunt, Jasmine (Durbin) [Jasmine_Hunt@durbin.senate.gov]
Subject: Senate TSCA TA request on preemption and science

Michal,
I'm circulating the TA request. Timing on response? Thanks,
Sven

On Jul 9, 2015, at 1:09 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

We will also need some TA on the language below, which is a potential alternative to the science prong on the section 18a waiver. Basically trying to say "the science about the risk is solid, and the state requirement is designed to address that risk".

The statute or administrative action of the state or political subdivision of the state is designed to address a risk of a chemical substance under the conditions of use that is based on information that is consistent with section 3(A)(c)(3)(A)

From: Kaiser, Sven-Erik
Sent: Thursday, July 9, 2015 12:03 PM
To: Black, Jonathan (Tom Udall)
Cc: Karakitsos, Dimitri (EPW); Freedhoff, Michal (Markey); Hunt, Jasmine (Durbin)
Subject: Re: Senate TSCA TA Call on Fees and Budget

Yes- 1pm- call Personal Phone / Ex. 6 code Personal Phone / Ex. 6 Thanks,
Sven

On Jul 9, 2015, at 11:45 AM, "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov> wrote:

Our plan is to call at 1.

From: Kaiser, Sven-Erik
Sent: Wednesday, July 8, 2015 5:35 PM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW); Freedhoff, Michal (Markey); Hunt, Jasmine (Durbin)
Subject: Senate TSCA TA Call on Fees and Budget

Jonathan,
I'm getting folks together, let's say tentatively a call tomorrow, Thurs, July 9 at 1pm. Let me know if the time moves. Please call Personal Phone / Ex. 6, code Personal Phone / Ex. 6 Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Wednesday, July 08, 2015 4:01 PM
To: Kaiser, Sven-Erik
Cc: Karakitsos, Dimitri (EPW); Freedhoff, Michal (Markey); Hunt, Jasmine (Durbin); Black, Jonathan (Tom Udall)
Subject: EPA T.A. Call on TSCA Fees and Budget

Sven, we are meeting from 1130-2pm tomorrow. One of the topics of discussion will be TSCA fees and the budget, specifically, how to key the minimum appropriations to ensure that EPA can set user fees.

We'd like to know how OMB A11 intersects with the budgeting and what is covered in the TSCA office.

Our preference is to call in around 1pm if possible. We'd also like to include Dem and GOP Senate Appropriations staff.

Others can chime in about the things they'd like to ask about.

Thanks,
---Jonathan

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/26/2015 5:10:27 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Albritton, Jason (EPW) [Jason_Albritton@epw.senate.gov]; Joseph, Avenel (Markey) [Avenel_Joseph@markey.senate.gov]
Subject: Markey TSCA TA request on judicial review

Michal,
Responding to your technical assistance request, the language changes look okay to EPA.

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

On Apr 26, 2015, at 6:23 AM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Sven - can you check to see if this works? It seems like it could be redundant based on your earlier TA but I'd like your take.

Thanks
Michal

From: Lowell, Heather (Legis Counsel) <Heather_Lowell@slc.senate.gov>
Sent: Saturday, April 25, 2015 8:10 PM
To: Freedhoff, Michal (Markey)
Cc: Johnson-Weider, Michelle (Legis Counsel); Albritton, Jason (EPW); Joseph, Avenel (Markey)
Subject: RE: Rekeyed amendments attached (arp15213)

From: Freedhoff, Michal (Markey)
Sent: Saturday, April 25, 2015 4:21 PM
To: Lowell, Heather (Legis Counsel)
Cc: Johnson-Weider, Michelle (Legis Counsel); Albritton, Jason (EPW); Joseph, Avenel (Markey); Freedhoff, Michal (Markey)
Subject: Re: Rekeyed amendments attached (arp15201, 202, 203, 205, 207)

For ARP 15205

Instead of amdt as currently drafted, change text as follows:

- strike section 19(c)(1)(B) of TSCA entirely, which will mean some conforming changes to the managers pkg
- in 19(c)(1)(A) of TSCA, strike "except as otherwise provided in subparagraph (B)"

Might be other conforming changes as well, I think I see one in 19(c)(C), though it is possible that is amended in the managers pkg as well.

Thanks
Michal

From: Lowell, Heather (Legis Counsel)
Sent: Saturday, April 25, 2015 7:41 AM
To: Freedhoff, Michal (Markey)
Cc: Johnson-Weider, Michelle (Legis Counsel)
Subject: Rekeyed amendments attached (arp15201, 202, 203, 205, 207)

Here you go, Michal.
<ARP15213.pdf>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/26/2015 4:05:02 PM
To: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: Udall Inhofe TSCA TA on Articles

Dimitri,
This responds to your technical assistance request on additional assessments.

Add a new paragraph (4) to section 4A(c), as follows:

(4) ADDITIONAL WORK PLAN CHEMICALS FOR SAFETY ASSESSMENT AND SAFETY DETERMINATION – In the case of a request under paragraph (1) with respect to a chemical substance identified by the Administrator in the October 2014 Work Plan and subsequent updates, the 15 percent cap specified in paragraph (3)(A) shall not apply.

Renumber paragraphs (4) and (5) of section 4A(c) as (5) and (6).

In section 26(b)(3)(E), add at the end of the existing text: ", except that for substances subject to section 4A(c)(4), the Administrator shall establish the fee at a level sufficient to defray 50 percent of such costs."

EPA believes the effect of this would be to allow an unlimited number of chemicals nominated by industry that are also on the work plan list to be added to the list of chemicals scheduled for safety assessments and safety determinations. As with the current drafting, these would not be high priority chemicals under the bill but rather "additional priorities". As such, 1. the decision to grant such a request would not trigger high priority preemption under sec 18(b); 2. the completion of a safety determination for one of these chemicals would not trigger the obligation to add a new chemical to the high priority list; and 3. the addition of these "additional priority" chemicals would not reduce the number of chemicals that need to be maintained on the high priority list under section 4A(a)(2) and (3).

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

On Apr 25, 2015, at 9:03 PM, "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov> wrote:

Thanks Sven - unfortunately one more request for you that Jonathan and I just discussed with Jim.

Can we please have some help drafting a new subsection in 4A after "Additional Priorities for Safety Assessments and Determinations" called "Additional Workplan Chemicals for Safety Assessments and Determinations." Might be better as part of (c) - I leave that to you all.

The idea being that if manufacturers or processors request a chemical already identified as a work plan priority by EPA, the agency can accept as many as they are able to handle (no cap) at their discretion and with a new 50% user fee.

Hope that makes sense, please let me know if you have any questions and thanks again.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Saturday, April 25, 2015 05:55 PM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW)
Subject: Udall Inhofe TSCA TA on Articles

Jonathan and Dimitri,
This follows up on your earlier request on articles. Attached please find the requested technical assistance. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/26/2015 11:02:20 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Albritton, Jason (EPW) [Jason_Albritton@epw.senate.gov]; Joseph, Avenel (Markey) [Avenel_Joseph@markey.senate.gov]
Subject: Re: TA request - substantial evidence - Fw: Rekeyed amendments attached (arp15213)

Michal,
Got it. Will take a look. Thanks,
Sven

On Apr 26, 2015, at 6:23 AM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Sven - can you check to see if this works? It seems like it could be redundant based on your earlier TA but I'd like your take.

Thanks
Michal

From: Lowell, Heather (Legis Counsel) <Heather_Lowell@slc.senate.gov>
Sent: Saturday, April 25, 2015 8:10 PM
To: Freedhoff, Michal (Markey)
Cc: Johnson-Weider, Michelle (Legis Counsel); Albritton, Jason (EPW); Joseph, Avenel (Markey)
Subject: RE: Rekeyed amendments attached (arp15213)

From: Freedhoff, Michal (Markey)
Sent: Saturday, April 25, 2015 4:21 PM
To: Lowell, Heather (Legis Counsel)
Cc: Johnson-Weider, Michelle (Legis Counsel); Albritton, Jason (EPW); Joseph, Avenel (Markey); Freedhoff, Michal (Markey)
Subject: Re: Rekeyed amendments attached (arp15201, 202, 203, 205, 207)

For ARP 15205

Instead of amdt as currently drafted, change text as follows:

- strike section 19(c)(1)(B) of TSCA entirely, which will mean some conforming changes to the managers pkg
- in 19(c)(1)(A) of TSCA, strike "except as otherwise provided in subparagraph (B)"

Might be other conforming changes as well, I think I see one in 19(c)(C), though it is possible that is amended in the managers pkg as well.

Thanks
Michal

From: Lowell, Heather (Legis Counsel)

Sent: Saturday, April 25, 2015 7:41 AM
To: Freedhoff, Michal (Markey)
Cc: Johnson-Weider, Michelle (Legis Counsel)
Subject: Rekeyed amendments attached (arp15201, 202, 203, 205, 207)

Here you go, Michal.
<ARP15213.pdf>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/8/2015 2:20:07 PM
To: 'Couri, Jerry' [JerryCouri@mail.house.gov]; McCarthy, David [David.McCarthy@mail.house.gov]
Subject: RE: HEC Briefing Request on TSCA Issues

Jerry – EPA availabilities for the requested briefing. Can be in person or by phone at your convenience.
Thurs, July 9, 9-11, 12-1:30, 2-6
Fri, July 10, 11-1, 2-4:30

Please let me know if any of those times work for you. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Couri, Jerry [mailto:JerryCouri@mail.house.gov]
Sent: Tuesday, July 07, 2015 5:37 PM
To: Kaiser, Sven-Erik; McCarthy, David
Subject: Re: HEC Briefing Request on TSCA Issues

That's correct. Any day this week would work.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik
Sent: Tuesday, July 7, 2015 5:08 PM
To: Couri, Jerry; McCarthy, David
Subject: HEC Briefing Request on TSCA Issues

Jerry,
Thank you for the request. I'll check on availability -- are there dates and times this week we should avoid? I'm thinking this is a possible precursor to a member forum that might be as early as next week. Please let me know if any additional questions. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Couri, Jerry [mailto:JerryCouri@mail.house.gov]
Sent: Tuesday, July 07, 2015 2:49 PM
To: Kaiser, Sven-Erik
Cc: McCarthy, David
Subject: Can we get TA/briefing this week on

The 5 TSCA section 8 issues mentioned in the Committee report. It would be Dave, myself, and possibly Jackie.

Gerald S. Couri
Senior Environmental Policy Advisor | Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Building | 202.226.9603 (direct)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/25/2015 6:24:57 PM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Udall TA on "May" for CBI section

Jonathan,
Responding to your request for technical assistance, this looks okay to EPA, no concerns.

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460

202-566-2753

On Apr 24, 2015, at 1:01 PM, "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov> wrote:

Also… any concerns from EPA with these changes?

The "may" is in clause 7 of S.697 as amended and corresponds to TSCA:

http://www.epw.senate.gov/tsca.pdf
<image004.png>
From the latest draft of S.697:

<image001.png>

<image002.png>
<image005.png>

From: Karakitsos, Dimitri (EPW)
Sent: Friday, April 24, 2015 12:04 PM
To: Black, Jonathan (Tom Udall); Wallace, Andrew (Tom Udall)

Under existing law there is a series of places where CBI "shall" and "may" be disclosed. As far as we know there have been no identified problems with where information "may" be disclosed – the very minor tweak in the bill changes one of the "shall" to conform with an existing law "may" and that is "may be disclosed when relevant in any proceeding

under this Act, except that disclosure in such a proceeding shall be made in such a manner as to preserve confidentiality to the extent practicable without impairing the proceeding"

Exact same language, just conforming the "may" with existing law.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/25/2015 6:05:45 PM
To: Michal Freedhoff [Michal_Freedhoff@markey.senate.gov]; Bettina Poirier [Bettina_Poirier@epw.senate.gov]; Jason Albritton [jason_albritton@epw.senate.gov]
Subject: Markey TA on substantial evidence
Attachments: Markey.TA.sbstntl evidence; ATT00001.htm

ichal,
Following up on your questions, please see the attached technical assistance on the standard of review. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

EPA does not think it is not correct that, if "substantial evidence" is stricken from the bill, we are left with a judicial review provision that doesn't specify the standard of review. Section 19(c)(1)(A) of TSCA provides that judicial review of TSCA rules and orders is "in accordance with chapter 7 of Title 5", "except as provided" in the ensuing paragraph (B). (B) in turn establishes the substantial evidence standard as the basis for review of specified TSCA rules (test rules under 4(a), rules determining that chemicals may present unreasonable risk under 5(b)(4), substantive control rules under 6(a), and PCB rules under 6(e)).

Chapter 7 of Title 5 (the Administrative Procedure Act) -- specifically section 706 -- provides for what's known as arbitrary-and-capricious review of all agency actions except where the applicable statute specifies formal, on-the-record procedures under APA section 556 or 557, rather than the usual notice and comment procedure under APA section 553. Nothing in TSCA specifies such formal procedures, and as a result, TSCA rules other than those specified in section 19(c)(1)(B) (e.g., significant new use rules under 5(a)(2)) are reviewed under the arbitrary and capricious standard under the current statute.

Thus, if the substantial evidence standard is deleted from TSCA, per the TA EPA provided earlier, the result would be that all TSCA actions would be reviewed under the arbitrary and capricious standard. To accomplish this, you would strike the lines of the bill stricken by your draft amendment[1], but instead of replacing them with the language you suggest, make the changes to the bill suggested in the earlier TA.

Aside from the fact that referencing the "arbitrary and capricious" standard is unnecessary, it's a shorthand that is not really an accurate statement of the APA standard of review. The fuller statement in the APA is that courts shall set aside agency actions found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" (section 706(2)(A)). In addition, that is only part of the basis for review of agency actions under the APA – there are several other standards courts are to apply, including judging whether agency actions are in excess of statutory authority, without observance of required procedure, etc. (section 706(2)). So, simply specifying that review is based on an "arbitrary and capricious" test would actually change the usual APA standard of review.

---

[1] The pagination you identified does not track with the version we are working off of – the 3/4 working draft. We understand, though, that the lines you intend to strike are the six lines amending TSCA section 19(c)(1)(B)(i), addressing "evidence in the rulemaking record" (lines 18-23 on p 154 of the 3/4 draft).

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/25/2015 4:22:55 PM
To: Adrian Deveny [Adrian_Deveny@merkley.senate.gov]
Subject: Merkley TA on Unreasonable Risk
Attachments: Merkley.TA.unrsnbl risk.docx; ATT00001.htm

Adrian,
Please see attached the requested technical assistance on unreasonable risk. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

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TA ON UNREASONABLE RISK STANDARD

Add the following new definition to section 3 of TSCA:

UNREASONABLE RISK: "Unreasonable risk" is a standard that ensures, without taking into consideration cost or other nonrisk factors, protection of health and the environment.

And have the following clarifying legislative history accompany the bill:

> The definition of the safety standard specifies that the determination of whether a chemical substance presents an unreasonable risk of injury to health or the environment shall be made without taking into consideration cost or other nonrisk factors. 'Unreasonable risk' in turn is defined as a risk-only standard that requires protection of health and the environment. A similar standard appears in section 3004 of the Resource Conservation and Recovery Act, and the conferees intend the phrase "protection of health and the environment" to be applied in a manner similar to the application of the standard under that statute.
>
> In adopting these definitions, the Conferees intend to depart from the interpretation of "unreasonable risk" adopted by the United States Court of Appeals for the Fifth Circuit in *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (1991). In that case, decided under TSCA prior to these amendments, the court stated:
>
> > The requirement that the risk be "unreasonable" necessarily involves a balancing test like that familiar in tort law: The regulation may issue if the severity of the injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation itself imposes upon manufacturers and consumers.
>
> In contrast to the cost-benefit interpretation followed prior to these amendments, the Conferees intend that, for all purposes under TSCA as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the determination of whether risks presented by a chemical substance are unreasonable will be based solely on consideration of risks to health or the environment from that chemical substance.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/25/2015 4:19:19 PM
To: Michal Freedhoff [Michal_Freedhoff@markey.senate.gov]; Bettina Poirier [Bettina_Poirier@epw.senate.gov]; Jason Albritton [jason_albritton@epw.senate.gov]
Subject: Markey TA on Unreasonable Risk
Attachments: Markey.TA.UNRSNBL RISK.doc; ATT00001.htm

Michal,
Please see attached the requested TA on reasonable risk. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions.
Thanks,
Sven

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

TA ON UNREASONABLE RISK STANDARD

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> In adopting these definitions, the Conferees intend to depart from the interpretation of "unreasonable risk" adopted by the United States Court of Appeals for the Fifth Circuit in *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (1991). In that case, decided under TSCA prior to these amendments, the court stated:
>
> > The requirement that the risk be "unreasonable" necessarily involves a balancing test like that familiar in tort law: The regulation may issue if the severity of the injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation itself imposes upon manufacturers and consumers.
>
> In contrast to the cost-benefit interpretation followed prior to these amendments, the Conferees intend that, for all purposes under TSCA as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the determination of whether risks presented by a chemical substance are unreasonable will be based solely on consideration of risks to health or the environment from that chemical substance.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/25/2015 3:51:57 PM
To: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Udall/Inhofe TA on judicial review of low priority decisions

Dimitri and Jonathan,
Additional thoughts. Actually, TSCA section 19 provides for review in the DC Circuit OR in the circuit where the petitioner resides or has its principal place of business. So it limits review to the US Courts of Appeals, but not specifically to the DC Circuit.

If you want a 60 day limited period of judicial review in the DC Circuit only for prioritization decisions, there probably needs to be a separate provision, but in section 19, not section 18. Please let me know if any additional questions.
Thanks,
Sven

On Apr 24, 2015, at 8:15 PM, "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov> wrote:

We want it all at the dc court of appeals - if we don't change anything are we good?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 24, 2015 08:13 PM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW)
Subject: Udall TA on judicial review of low priority decisions

Jonathan,
We brought it to your attention because we understand that some folks are looking for judicial review of the low priority decisions to go the district courts. The language in section 19 may have the unintended impact of sending them to the higher level Court of Appeals, creating a conflict if language is adopted providing judicial review of low priority decisions in district courts. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Friday, April 24, 2015 7:54 PM
To: Kaiser, Sven-Erik; Karakitsos, Dimitri (EPW)
Subject: RE: Inhofe Udall TSCA TA on Articles and PBTS

Thanks Sven.

I don't understand your point about the TSCA court.

TSCA is subject to the U.S. Courts of Appeals, and so would a low-priority decision?

I'm not familiar with all of these courts. That's different from the U.S. Court of Appeals for the District of Columbia Circuit?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 24, 2015 7:50 PM
To: Karakitsos, Dimitri (EPW); Black, Jonathan (Tom Udall)
Subject: Inhofe Udall TSCA TA on Articles and PBTS

Dimitri and Jonathan,
Attached please find the requested technical assistance. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

There is an additional issue we would like to flag as technical assistance. It looks like section 19(a)(1)(B) is modified by the bill so that any order under Title I of TSCA is already subject to exclusive judicial review in the U.S. Courts of Appeals. Review is not subject to the 60 day time bar. A low priority designation is an "order" under the Administrative Procedure Act. Hence, low priority designations are already sent to exclusive review in the Courts of Appeals, under Section 19. This language may need to be resolved in order depending on your intent regarding judicial review of low priority designations. Please let me know if you have any additional questions. Thanks,
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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/25/2015 2:21:22 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Albritton, Jason (EPW) [Jason_Albritton@epw.senate.gov]; Poirier, Bettina (EPW) [Bettina_Poirier@epw.senate.gov]
Subject: Re: Markey Boxer TSCA TA on substantial evidence amendment

Michal,
Got it, circulating. Thanks,
Sven

On Apr 25, 2015, at 10:10 AM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

Some follow up with you on the substantial evidence amendment.

First of all, the right page/line. #s of the mgrs text to refer to is page 147 lines 12-17. That part of the bill amends the judicial review section of tsca. The reason why we drafted it the way we did was that it is basically now drafted as a technical amdt to their text. If we delete "substantial evidence" and don't replace it with anything, then we are left with a judicial review section of underlying tsca that doesn't specify a standard of review, which seemed odd to us.

Could you confirm that our way of drafting this works technically, even if it is redundant with APA?

Thanks
Michal

Original Message
From: Kaiser, Sven-Erik
Sent: Friday, April 24, 2015 7:28 PM
To: Freedhoff, Michal (Markey); Albritton, Jason (EPW); Poirier, Bettina (EPW)
Subject: Markey Boxer TSCA TA on 9 amendments

Michal,
In response to your request, please see attached technical assistance on the 9 potential amendments. This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions.

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

-----Original Message-----
From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, April 24, 2015 10:32 AM
To: Kaiser, Sven-Erik; Albritton, Jason (EPW); Poirier, Bettina (EPW)
Subject: RE: For Call at 9:30

Here are a number of amendments for TA purposes. Jason may have more to share. We also have unreasonable risk flagged for you on a separate track, and will continue that dialogue as we review what you sent us yesterday.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/25/2015 1:36:34 PM
To: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: Inhofe Udall TSCA TA on Articles and PBTS

Dimitri,
We have a slight preference for the first one, just a feel thing, nothing particular we can articulate. Thanks,
Sven

On Apr 25, 2015, at 9:13 AM, "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov> wrote:

Both just slightly different formulations with "to the extent necessary" in different spots. The bold text is before that line in one and after in the other. Didn't know if either formulation would be preferable.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Saturday, April 25, 2015 09:07 AM
To: Karakitsos, Dimitri (EPW)
Cc: Black, Jonathan (Tom Udall)
Subject: Re: Inhofe Udall TSCA TA on Articles and PBTS

Dimitri,
We're confused. I thought the formulations were what you sent below. Is there further question on them or is there something else I am missing? Thanks,
Sven

On Apr 25, 2015, at 8:49 AM, "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov> wrote:

Thanks Sven - does you have a formulation for either the first or second version?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Saturday, April 25, 2015 08:39 AM
To: Karakitsos, Dimitri (EPW)
Cc: Black, Jonathan (Tom Udall)
Subject: Re: Inhofe Udall TSCA TA on Articles and PBTS

Dimitri, we are okay with your formulation for section 6 articles language with a preference for "the" over "any". For the section 5 articles language we propose to add "potential " in front of risk. Please let me know if any additional questions. Thanks,
Sven

On Apr 24, 2015, at 10:11 PM, "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov> wrote:

Sven – one additional question on this. Appreciate the language and think we are very close. I totally agree with the intent of comment 1 that "there is no way to meet this test without identifying some risk from the chemical substance in the article and explaining why that risk would preclude a determination that the chemical substance is likely to meet the safety standard." My question is can we please be a little more explicit about that in the language? What if the full text of the articles provision said one of these two things:

"The Administrator shall, in selecting among prohibitions and other restrictions apply such prohibitions or other restrictions to articles containing the chemical substance only to the extent necessary ***to address the/any identified risks in order*** to determine that the chemical substance is likely to meet the safety standard."

"The Administrator shall, in selecting among prohibitions and other restrictions apply such prohibitions or other restrictions to articles containing the chemical substance only ***to address the/any identified risks*** to the extent necessary to determine that the chemical substance is likely to meet the safety standard."

Any help with this would be greatly appreciated.

Thanks again

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 24, 2015 7:50 PM
To: Karakitsos, Dimitri (EPW); Black, Jonathan (Tom Udall)
Subject: Inhofe Udall TSCA TA on Articles and PBTS

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Message

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Sent: 4/25/2015 12:35:16 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Albritton, Jason (EPW) [Jason_Albritton@epw.senate.gov]; Poirier, Bettina (EPW) [Bettina_Poirier@epw.senate.gov]
Subject: Re: Sen. Markey TSCA TA request on unreasonable risk

Michal,
We're on it and expect to have something today. Thanks,
Sven

On Apr 25, 2015, at 6:02 AM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Also just following up - we had requested some additional TA on a definition of "unreasonable risk". Apologies if I missed it, but just wondering on ETA if I hadn't?
Thanks
Michal

From: Kaiser, Sven-Erik
Sent: Friday, April 24, 2015 7:33 PM
To: Freedhoff, Michal (Markey); Albritton, Jason (EPW); Poirier, Bettina (EPW)
Subject: RE: Sen. Markey TSCA TA request on throughput

Michal,
We think the statements on throughput are mutually correct. As Jim said to Sen. Markey during the hearing, at the current level of technology, if working at the minimum pace under the bill, it could take more than 100 years to finish assessing 1,000 chemicals. Per the TA we sent, ramping up the pace to completing assessments on 1,000 chemicals in 25 years depends on two assumptions -- that later assessments will be quicker since higher priority chemicals go first and that technology will emerge. The 40 assessments per year comes from our experience in pesticides that even if fully resourced, which this bill does not do, there seems to be a functional limit of around 40 assessments per year. Please let me know if you would like more discussion on this.
Thanks,
Sven

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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, April 24, 2015 5:47 PM
To: Kaiser, Sven-Erik; Albritton, Jason (EPW)
Cc: Freedhoff, Michal (Markey)
Subject: RE: Sen. Markey TSCA TA request on throughput

Sven

I'm trying to square the TA you gave us below with Jim Jones testimony at our hearing (pasted). Is the issue that it might take more than 25 years to assess 1,000 chemicals because it will take awhile for the technology to come together? All I did to get to the #s in our amendment was divide 1000 chemicals by the pace of 40/year that Jim said could be done.

Thanks
Michal

Senator Inhofe. A lot of discussion has gone on over how many chemicals EPA should be required to review at any time, any particular time. If EPA had access to an unlimited amount of resources or user fees, is there a limit to EPA's capacity to review, with your current staffing, to review chemicals?

Mr. Jones. I believe there is. I am sorry, this will take more than one word. But from my experience, even in the pesticides program, where we have about three times as many resources under the Food Quality Protection Act, the most output we are able to do is in the range of about 40 a year. Based on that experience, I would expect that would probably be true in the TSCA sense as well.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
218 Russell Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, April 23, 2015 5:21 PM
To: Freedhoff, Michal (Markey); Albritton, Jason (EPW)
Subject: Fwd: Sen. Markey TSCA TA request on throughput

Michal,
In response to your request, below is technical assistance responding to questions on throughput. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the

policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

To: "Vaught, Laura" <Vaught.Laura@epa.gov>
Subject: more TA requested

Hi Laura

We drafted up an amendment to increase throughput and fees such that the 1,000 chemicals most in need of assessment are completed within 25 years. Can you please provide TA? And generally, would you agree that it is possible to ramp up over time because it is likely the first assessments that will be the more complicated/lengthy?

Response: While it is likely that we will be able to ramp up the pace of assessments over time, the pace will be contingent on two factors. We anticipate that the prioritization process for high-priority substances would result in those assessments prioritized later in the process to move more quickly. However, to complete this level of assessment in 25 years, there would need to significant breakthroughs in computational toxicology technologies currently under development. These technologies could have the potential to markedly increase throughput although EPA cannot predict, at present, when those technologies might become available for this purpose.

Thanks
Michal

On page 33, line 17, strike insert "as soon as practicable, but not later than" before "3 years".

On page 33, line 21, strike "20" and insert "40".

On page 34, line 2, strike "and".

On page 34, line 8, strike "25" and insert "100".

On page 34, line 14, strike the period and insert a semicolon.

On page 34, between lines 14 and 15, insert the following:

(iii) as soon as practicable, but not later than 10 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 300 high-priority substances have undergone or are undergoing the process established in section 6(a); and

(iv) as soon as practicable, but not later than 25 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 1,000 high-priority substances have undergone or are undergoing the process established in section 6(a).

On page 161, line 15, insert "clauses (i), (ii), and (iii) of" after "identified in".

On page 161, line 16, strike ", not to exceed $18,000,000" and insert "and 75 percent of the costs of conducting the activities identified in clauses (iv) and (v) of paragraph (2)(A)".

Message

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Sent: 4/25/2015 12:24:11 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Albritton, Jason (EPW) [Jason_Albritton@epw.senate.gov]; Poirier, Bettina (EPW) [Bettina_Poirier@epw.senate.gov]
Subject: Re: Sen. Markey TSCA TA request on throughput

Checking

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Message

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Sent: 4/25/2015 2:13:14 AM
To: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: Inhofe Udall TSCA TA on Articles and PBTS

Got it- checking

On Apr 24, 2015, at 10:11 PM, "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov> wrote:

Sven – one additional question on this. Appreciate the language and think we are very close. I totally agree with the intent of comment 1 that "there is no way to meet this test without identifying some risk from the chemical substance in the article and explaining why that risk would preclude a determination that the chemical substance is likely to meet the safety standard." My question is can we please be a little more explicit about that in the language? What if the full text of the articles provision said one of these two things:

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Sent: 4/25/2015 12:16:28 AM
To: 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: RE: Udall TA on judicial review of low priority decisions

If that's your intent - yes

Sven-Erik Kaiser
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From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Friday, April 24, 2015 8:15 PM
To: Kaiser, Sven-Erik; Black, Jonathan (Tom Udall)
Subject: Re: Udall TA on judicial review of low priority decisions

We want it all at the dc court of appeals - if we don't change anything are we good?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 24, 2015 08:13 PM
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Subject: Udall TA on judicial review of low priority decisions

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Subject: Inhofe Udall TSCA TA on Articles and PBTS

Dimitri and Jonathan,
Attached please find the requested technical assistance. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

There is an additional issue we would like to flag as technical assistance. It looks like section 19(a)(1)(B) is modified by the bill so that any order under Title I of TSCA is already subject to exclusive judicial review in the U.S. Courts of Appeals. Review is not subject to the 60 day time bar. A low priority designation is an "order" under the Administrative Procedure Act. Hence, low priority designations are already sent to exclusive review in the Courts of Appeals, under Section 19. This language may need to be resolved in order depending on your intent regarding judicial review of low priority designations. Please let me know if you have any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/24/2015 11:50:10 PM
To: 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Inhofe Udall TSCA TA on Articles and PBTS
Attachments: Udall Inhofe.TSCA TA.Articles and PBTs.docx

Dimitri and Jonathan,
Attached please find the requested technical assistance. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

There is an additional issue we would like to flag as technical assistance. It looks like section 19(a)(1)(B) is modified by the bill so that any order under Title I of TSCA is already subject to exclusive judicial review in the U.S. Courts of Appeals. Review is not subject to the 60 day time bar. A low priority designation is an "order" under the Administrative Procedure Act. Hence, low priority designations are already sent to exclusive review in the Courts of Appeals, under Section 19. This language may need to be resolved in order depending on your intent regarding judicial review of low priority designations. Please let me know if you have any additional questions. Thanks,
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Technical Assistance on Articles and PBTS

§ 5(d)(4) Restrictions.—

…

"(D) ARTICLES.—The Administrator shall, in selecting among prohibitions and other restrictions ~~that the Administrator determines are sufficient to ensure that the chemical substance is likely to meet the safety standard~~, apply such prohibitions or other restrictions to articles containing the chemical substance only to the extent necessary to **determine that the chemical substance is likely to meet the safety standard**~~mitigate the identified potential risk from the chemical substance in such article~~.;

"(E) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines ranks high for persistence and bioaccumulation, the Administrator shall, in selecting among prohibitions and other restrictions**, make a choice** that ~~the Administrator determines are sufficient to~~ ensure**s** that the chemical substance is likely to meet the safety standard, **and that furthermore** reduces potential exposure to the substance to the maximum extent practicable.

§ 6(d)(2) Scope.—

….

"(C) ARTICLES.—The Administrator shall, in selecting among prohibitions and other restrictions ~~that the Administrator determines are sufficient to ensure that the chemical substance meets the safety standard~~, apply such prohibitions or other restrictions to articles containing the chemical substance only to the extent necessary to **ensure that the chemical substance meets the safety standard**~~mitigate the identified risk from the chemical substance in such article~~.;

"(D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines ranks high for persistence and bioaccumulation, the Administrator shall , in selecting among prohibitions and other restrictions**, make a choice** that ~~the Administrator determines are sufficient to~~ ensure**s** that the chemical substance meets the safety standard, **and that furthermore** reduces exposure to the maximum extent practicable.

Commented [A1]: Drafting Justification:

(1)There is no way to meet this test without identifying some risk from the chemical substance in the article and explaining why that risk would preclude a determination that the chemical substance is likely to meet the safety standard.

(2)Edits are to avoid ambiguity about whether "mitigate" is a separate safety standard,

(3)Edits are also to avoid the original analytical problems with the language from § 3A, of suggesting EPA has a burden to separately identify risks with respect to each "such article"

Commented [A2]: To clarify that the maximum extent practicable language is on top of likely meeting the safety standard, not instead of it.

Commented [A3]: Drafting Justification:

(1)There is no way to meet this test without identifying some risk from the chemical substance in the article and explaining why that risk would lead to the chemical substance not meeting the safety standard.

(2)Edits are to avoid ambiguity about whether "mitigate" is a separate safety standard,

(3)Edits are also to avoid the original analytical problems with the language from § 3A, of suggesting EPA has a burden to separately identify risks with respect to each "such article"

Commented [A4]: To clarify that the maximum extent practicable language is on top of meeting the safety standard, not instead of it.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

§ 6(e) Immediate Effect.—The Administrator may declare a proposed rule under subsection (d)~~(1)~~ to be effective on publication of the rule

Commented [A5]: Not all rules are under (d)(1) if there are expedited action rules.

***

§ 6(i) Expedited Action.—

(1) IN GENERAL.--Notwithstanding sections 3A, and 4A, subsections (a), (b), (c), and (d)(1), the Administrator may promulgate a rule under subsection (d) establishing restrictions necessary to ensure that a chemical substance meets the safety standard if—

(A) the chemical substance is listed in the 2014 update of the TSCA Work Plan for Chemical Assessments; and

(B) the chemical substance has been—

(i) classified by the International Agency for Research on Cancer as a Group 1, 2A, or 2B substance

(ii) determined by the National Academy of Sciences, in a publicly issued report, to be a known or reasonably anticipated human carcinogen or to pose a risk to human health

(iii) evaluated by the National Toxicology Program and listed in the Report on Carcinogens as a known or reasonably anticipated human carcinogen; or

(iv) subject to a restriction or prohibition enacted by a foreign country

(2) CONTRIBUTION TO PROGRESS ON ADDITIONAL CHEMICAL REVIEWS.—A chemical substance that is the subject of a final rule promulgated under subsection (d), as authorized by this subsection, shall be added, for purposes of section 4A(2)(c), to the count of high-priority substances that have undergone the process established in section 6(a),

Commented [A6]: This is to ensure that completed action under 6(i) is deemed the equivalent of taking a chemical all the way through high-priority designation, safety determination, and risk management, for purposes of the TSCA throughput benchmarks in 4A.

(3) TIMELY RESOLUTION.—The Administrator shall take final action within [X] years on any proposal to issue a rule under subsection (d) that is authorized by this subsection

Commented [A7]: Since 6(a) deadline provisions don't directly apply, this provides comparable assurance that EPA will timely withdraw or finalize any proposed expedited action.

(4) AVAILABILITY OF FEES.--The promulgation of a rule pursuant to subsection (d), as authorized by this subsection, is necessary rulemaking for purposes of Section 26(b)(2)(A)(v).

Commented [A8]: So EPA can use TSCA money.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/24/2015 11:33:38 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; Albritton, Jason (EPW) [Jason_Albritton@epw.senate.gov]; Poirier, Bettina (EPW) [Bettina_Poirier@epw.senate.gov]
Subject: RE: Sen. Markey TSCA TA request on throughput

Michal,
We think the statements on throughput are mutually correct. As Jim said to Sen. Markey during the hearing, at the current level of technology, if working at the minimum pace under the bill, it could take more than 100 years to finish assessing 1,000 chemicals. Per the TA we sent, ramping up the pace to completing assessments on 1,000 chemicals in 25 years depends on two assumptions -- that later assessments will be quicker since higher priority chemicals go first and that technology will emerge. The 40 assessments per year comes from our experience in pesticides that even if fully resourced, which this bill does not do, there seems to be a functional limit of around 40 assessments per year. Please let me know if you would like more discussion on this.
Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, April 24, 2015 5:47 PM
To: Kaiser, Sven-Erik; Albritton, Jason (EPW)
Cc: Freedhoff, Michal (Markey)
Subject: RE: Sen. Markey TSCA TA request on throughput

Sven

I'm trying to square the TA you gave us below with Jim Jones testimony at our hearing (pasted). Is the issue that it might take more than 25 years to assess 1,000 chemicals because it will take awhile for the technology to come together? All I did to get to the #s in our amendment was divide 1000 chemicals by the pace of 40/year that Jim said could be done.

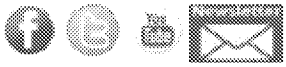
Thanks
Michal

Senator Inhofe. A lot of discussion has gone on over how many chemicals EPA should be required to review at any time, any particular time. If EPA had access to an unlimited amount of resources or user fees, is there a limit to EPA's capacity to review, with your current staffing, to review chemicals?

Mr. Jones. I believe there is. I am sorry, this will take more than one word. But from my experience, even in the pesticides program, where we have about three times as many resources under the Food Quality Protection Act, the most output we are able to do is in the range of about 40 a year. Based on that experience, I would expect that would probably be true in the TSCA sense as well.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
218 Russell Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, April 23, 2015 5:21 PM
To: Freedhoff, Michal (Markey); Albritton, Jason (EPW)
Subject: Fwd: Sen. Markey TSCA TA request on throughput

Michal,

In response to your request, below is technical assistance responding to questions on throughput. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

To: "Vaught, Laura" <Vaught.Laura@epa.gov>
Subject: more TA requested

Hi Laura

We drafted up an amendment to increase throughput and fees such that the 1,000 chemicals most in need of assessment are completed within 25 years. Can you please provide TA? And generally, would you agree that it is possible to ramp up over time because it is likely the first assessments that will be the more complicated/lengthy?

Response: While it is likely that we will be able to ramp up the pace of assessments over time, the pace will be contingent on two factors. We anticipate that the prioritization process for high-priority substances would result in those assessments prioritized later in the process to move more quickly. However, to complete this level of assessment in 25 years, there would need to significant breakthroughs in computational toxicology technologies currently under development. These technologies could have the potential to markedly increase throughput although EPA cannot predict, at present, when those technologies might become available for this purpose.

Thanks

Michal

On page 33, line 17, strike insert "as soon as practicable, but not later than" before "3 years".

On page 33, line 21, strike "20" and insert "40".

On page 34, line 2, strike "and".

On page 34, line 8, strike "25" and insert "100".

On page 34, line 14, strike the period and insert a semicolon.

On page 34, between lines 14 and 15, insert the following:

> (iii) as soon as practicable, but not later than 10 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 300 high-priority

substances have undergone or are undergoing the process established in section 6(a); and

(iv) as soon as practicable, but not later than 25 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 1,000 high-priority substances have undergone or are undergoing the process established in section 6(a).

On page 161, line 15, insert "clauses (i), (ii), and (iii) of" after "identified in".

On page 161, line 16, strike ", not to exceed $18,000,000" and insert "and 75 percent of the costs of conducting the activities identified in clauses (iv) and (v) of paragraph (2)(A)".

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/24/2015 11:28:35 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; Albritton, Jason (EPW) [Jason_Albritton@epw.senate.gov]; Poirier, Bettina (EPW) [Bettina_Poirier@epw.senate.gov]
Subject: Markey Boxer TSCA TA on 9 amendments
Attachments: Markey.TSCA TA.9 Amends.docx

Michal,
In response to your request, please see attached technical assistance on the 9 potential amendments. This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions.

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

-----Original Message-----
From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, April 24, 2015 10:32 AM
To: Kaiser, Sven-Erik; Albritton, Jason (EPW); Poirier, Bettina (EPW)
Subject: RE: For Call at 9:30

Here are a number of amendments for TA purposes. Jason may have more to share. We also have unreasonable risk flagged for you on a separate track, and will continue that dialogue as we review what you sent us yesterday.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

TA on LOWPRIORITYJUDICIAL

The reference to commencing a civil action is confusing, since a suit to challenge an agency action is not normally referred to as a civil action. In addition, this provision does not belong in section 18, since it now no longer has anything to do with preemption. In lieu of your suggested amendment, we suggest adding "a designation under section 4A(b)(4)" to the list of actions subject to time-limited appellate review in section 19(a)(1)(A), in order to integrate this into the general TSCA judicial review provision.

More broadly, note that as § 19(a)(1)(B) is modified by the bill, any order under Title I of TSCA is already subject to exclusive judicial review in the U.S. Courts of Appeals. Review is not subject to the 60-day time bar. A low-priority designation is an "order" under the Administrative Procedure Act. Hence, low-priority designations are already sent to exclusive review in the Courts of Appeals, under Section 19. This conflict would need to be resolved in order to effectuate your intent to have judicial review of low-priority designations occur in the U.S. District Courts.

TA on COSTBENEFIT

The phrase "to ensure that a chemical substance meets the safety standard" (p.1 lines 6-7) seems superfluous, since that is a requirement of all rules under section 6(d)(1), and it could suggest that not all rules under section 6(d)(1) are subject to that requirement.

The draft suggests that there will always be 1 or more alternative chemical substances relevant to a section 6 rulemaking, which is not the case. To avoid that implication, we suggest adding "any" before "1" on p 1 line 10.

On p 2 lines 12-13: a similar comment about what it means to take chemical alternatives into consideration.

TA on IMPLEMENTATIONDATE

Drafting looks ok on this.

TA on VOIDPREEMPTIONCOMPLIANCEDATE

The amendments would make 18(b) superfluous, since it would not preempt anything that would not already be preempted by 18(a)(1)(B).

TA on WORSTOFWORST

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The following re-drafting would accomplish the intended objective and: (1) Further harmonize with existing provisions in the bill; (2) Avoid the need for an additional determination; (3) Clarify relationship to throughput requirements; (4) Clarify expectation of timely resolution of action; and (5) Clarify that TSCA Implementation moneys are available to fund this:

§ 6(e) Immediate Effect.—The Administrator may declare a proposed rule under subsection (d)~~(1)~~ to be effective on publication of the rule

Commented [A1]: Not all rules are under (d)(1) if there are expedited action rules.

§ 6(i) Expedited Action.—

(1) IN GENERAL.--Notwithstanding sections 3A, and 4A, subsections (a), (b), (c), and (d)(1), the Administrator may promulgate a rule under subsection (d) establishing restrictions necessary to ensure that a chemical substance meets the safety standard if—

Commented [A2]: This casts a broader net over other provisions that might otherwise be in tension with the concept of expedited action.

(A) the chemical substance is listed in the 2014 update of the TSCA Work Plan for Chemical Assessments; and

(B) the chemical substance has been—

(i) classified by the International Agency for Research on Cancer as a Group 1, 2A, or 2B substance

(ii) determined by the National Academy of Sciences, in a publicly issued report, to be a known or reasonably anticipated human carcinogen or to pose a risk to human health

(iii) evaluated by the National Toxicology Program and listed in the Report on Carcinogens as a known or reasonably anticipated human carcinogen; or

(iv) subject to a restriction or prohibition enacted by a foreign country

(2) CONTRIBUTION TO PROGRESS ON ADDITIONAL CHEMICAL REVIEWS.—A chemical substance that is the subject of a final rule promulgated under subsection (d), as authorized by this subsection, shall be added, for purposes of section 4A(2)(c), to the count of high-priority substances that have undergone the process established in section 6(a),

Commented [A3]: This is to ensure that completed action under 6(i) is deemed the equivalent of taking a chemical all the way through high-priority designation, safety determination, and risk management, for purposes of the TSCA throughput benchmarks in 4A.

(3) TIMELY RESOLUTION.—The Administrator shall take final action within [X] years on any proposal to issue a rule under subsection (d) that is authorized by this subsection

Commented [A4]: Since 6(a) deadline provisions don't directly apply, this provides comparable assurance that EPA will timely withdraw or finalize any proposed expedited action.

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(4) AVAILABILITY OF FEES.--The promulgation of a rule pursuant to subsection (d), as authorized by this subsection, is necessary rulemaking for purposes of Section 26(b)(2)(A)(v).

Commented [A5]: So EPA can use TSCA money.

TA on COENFORCEMENT

If (as it appears) the intent is to allow states to establish and enforce requirements identical to EPA requirements, you should strike p 143 lines 18-20, in addition to the draft amendments you forwarded. If you want to preserve state authority to establish and enforce *reporting* requirements that are identical to EPA's, in addition to substantive regulatory requirements, you should also strike "not otherwise required by the Administrator under this Act or required under any other Federal law" on p 143 lines 6-8.

Apply the same comments to the draft amendments for pages 144 and 145.

TA on CURRENTTSCAWAIVERPLUSCOENFORCEMENT

The draft text allows EPA to exempt state laws "from the effective date under subsection (a)(1)(B)". It is not clear what it means to exempt a state law from an effective date. If the intent is to exempt state laws from preemption, this language does not accomplish that. A similar issue arises with the reference to (a)(1)(B) on p 2 line 18.

See above TA for the co-enforcement part

TA on SUBSTANTIAL EVIDENCE

It is difficult to follow the specific amendments you are suggesting to the bill, because the line numbers on your draft don't appear to align with the line number on our draft of the bill. But if (as it appears) your intention is to eliminate the substantial evidence standard from TSCA so that all EPA actions under TSCA are reviewed under the arbitrary and capricious standard, the simplest way to do that is to:

Strike section 19(c)(1)(B) entirely (note that much of it is already stricken by the bill); and
strike "except as otherwise provided in subparagraph (B)" from section 19(c)(1)(A).

There is no need to specify that review is under the arbitrary and capricious standard, as your draft amendment does; that is already provided for by existing

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section 19(c)(1)(A), except to the extent the substantial evidence standard applies under section 19(c)(1)(B).

TA on VOIDPREEMPTIONSTRIKE

This document eliminates section 18(b) "high-priority" preemption and make a number of conforming changes throughout the bill, including eliminating the corresponding provision for waiver of 18(b) preemption (18(f)(1)(B)). We have not scrubbed the bill to confirm that all conforming changes have been made. The new section 18(e)(1) appears identical to section 18(f)(1)(A) of the bill other than renumbering; if there are subtle wording changes, we didn't catch them.

This document also contains amendments to provide for co-enforcement that are identical or substantially identical to those provided in COENFORCEMENT. See our TA on that document for this portion.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/24/2015 7:20:10 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]; 'Poirier, Bettina (EPW)' [Bettina_Poirier@epw.senate.gov]; 'Albritton, Jason (EPW)' [Jason_Albritton@epw.senate.gov]
Subject: Sen Markey TSCA TA on Questions
Attachments: Markey.TSCA TA.Questions.docx

Michal,
In response to your request, attached is EPA's technical assistance on Sen. Markey's questions 7,8,9 and 10 from the SEPW TSCA Reform hearing. This technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

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Markey Questions

Q7. In 1989, EPA tried to ban asbestos under its TSCA authority, but industry successfully overturned the ban in court. The term in the Udall-Vitter bill that is used to define what is meant by "safe" contains the "unreasonable risk" language that was in part the subject of that litigation. Do you believe that the use of this same language that has already been the subject of litigation would increase the likelihood that EPA would be sued using some of the same arguments industry used to overturn the asbestos ban?

Response: The safety standard as defined in S. 697 includes language alters the meaning of "unreasonable risk" from current TSCA. That being said, we would not be surprised if litigants made similar arguments used in prior cases.

Q8. In 2014, a chemical safety case decided in the DC Circuit of the US Court of Appeals reiterated an earlier finding that "This court has acknowledged the difficulties of applying the substantial evidence test "to regulations which are essentially legislative and rooted in inferences from complex scientific and factual data, and which often necessarily involve highly speculative projections of technological development in areas wholly lacking in scientific and economic certainty." The Udall-Vitter bill includes this same "substantial evidence" standard, even though it can be a much harder standard to meet than the one used in other environmental laws. This standard was also part of industry's successful arguments to overturn EPA's asbestos ban. Do you agree that the so-called "substantial evidence" standard is not yet settled law, and that its use in this bill would increase the likelihood that EPA would be sued using some of the same arguments industry used to overturn the asbestos ban?

Response: EPA may be sued using some of the same arguments used in the asbestos case, in view of the retention of the "substantial evidence" standard. We note, though, that the DC Circuit, in the case the question refers to, remarked on "an 'emerging consensus' of the Courts of Appeals, that the difference between the two standards should not be 'exaggerate[d].'" We also note that whatever benefit might accrue to litigants under the standard would accrue both to industry and environmental litigants challenging EPA action.

Q9. In 1989, EPA tried to ban asbestos under its TSCA authority, but industry successfully overturned the ban in court. Asbestos is already banned in 54 countries, and exposure to it kills 10,000 Americans each year. Would the Udall-Vitter bill allow EPA to immediately propose a ban or restriction on asbestos, or would it have to complete a safety assessment first?

Response: EPA would have the discretion to prioritize asbestos immediately, but would not be required to. The safety assessment and determination processes described in the bill would need to be followed before any potential risk management could be promulgated.

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10. Persistent, bio-accumulative and toxic chemicals like mercury and PCBs are known to persist in the environment and accumulate in the body, and can include dangerous chemicals that pass from pregnant women to developing fetuses. Would the Udall-Vitter bill allow EPA to immediately propose a ban or restriction on these known dangers?

Response:

PCBs are already banned, by TSCA section 6(e). With respect to other PBT chemicals: EPA would have the discretion to prioritize these types of chemicals immediately, but would not be required to. The safety assessment and determination processes described in the bill would need to be followed before any potential risk management could be promulgated.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/24/2015 5:02:13 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: RE: "May" for CBI section

checking

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Friday, April 24, 2015 1:01 PM
To: Kaiser, Sven-Erik
Subject: "May" for CBI section

Also… any concerns from EPA with these changes?

The "may" is in clause 7 of S.697 as amended and corresponds to TSCA:

http://www.epw.senate.gov/tsca.pdf

SEC. 14. DISCLOSURE OF DATA.

(a) IN GENERAL.—Except as provided by subsection (b), any information reported to, or otherwise obtained by, the Administrator (or any representative of the Administrator) under this Act, which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section, shall, notwithstanding the provisions of any other section of this Act, not be disclosed by the Administrator or by any officer or employee of the United States, except that such information—

(1) shall be disclosed to any officer or employee of the United States—

(A) in connection with the official duties of such officer or employee under any law for the protection of health or the environment, or

(B) for specific law enforcement purposes;

(2) shall be disclosed to contractors with the United States and employees of such contractors if in the opinion of the Administrator such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States entered into on or after the date of enactment of this Act for the performance of work in connection with this Act and under such conditions as the Administrator may specify;

(3) shall be disclosed if the Administrator determines it necessary to protect health or the environment against an unreasonable risk of injury to health or the environment; or

(4) may be disclosed when relevant in any proceeding under this Act, except that disclosure in such a proceeding shall be made in such manner as to preserve confidentiality to the extent practicable without impairing the proceeding.

From the latest draft of S.697:

"(e) Exceptions to Protection From Disclosure.—Information described in subsection (a) ~~shall be disclosed if~~—

This change is simply to conform with current law that exception 7 is a "may" be disclosed instead of a "shall"

"(1) shall be disclosed if the information is to be disclosed to an officer or employee of the United States in connection with the official duties of the officer or employee—

"(A) under any law for the protection of health or the environment; or

"(B) for a specific law enforcement purpose;

"(2) shall be disclosed if the information is to be disclosed to a contractor of the United States and employees of that contractor—

"(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act; and

"(B) subject to such conditions as the Administrator may specify;

"(3) shall be disclosed if the Administrator determines that disclosure is necessary to protect health or the environment;

"(4) shall be disclosed if the information is to be disclosed to a State or political subdivision of a State, on written request, for the purpose of development, administration, or enforcement of a law, if—

"(A) 1 or more applicable agreements with the Administrator that conform with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information; and

"(B) the Administrator notifies the owner or [illegible] of the information [illegible]

"(5) shall be disclosed if a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

"(A) the statement of need and confidentiality agreement shall conform with the guidance issued under subsection (d)(3)(B);

"(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

"(i) the information is necessary for, or will assist in—

"(I) the diagnosis or treatment of 1 or more individuals; or

"(II) responding to an environmental release or exposure; and

"(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

"(C) the confidentiality agreement shall provide that the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the

agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

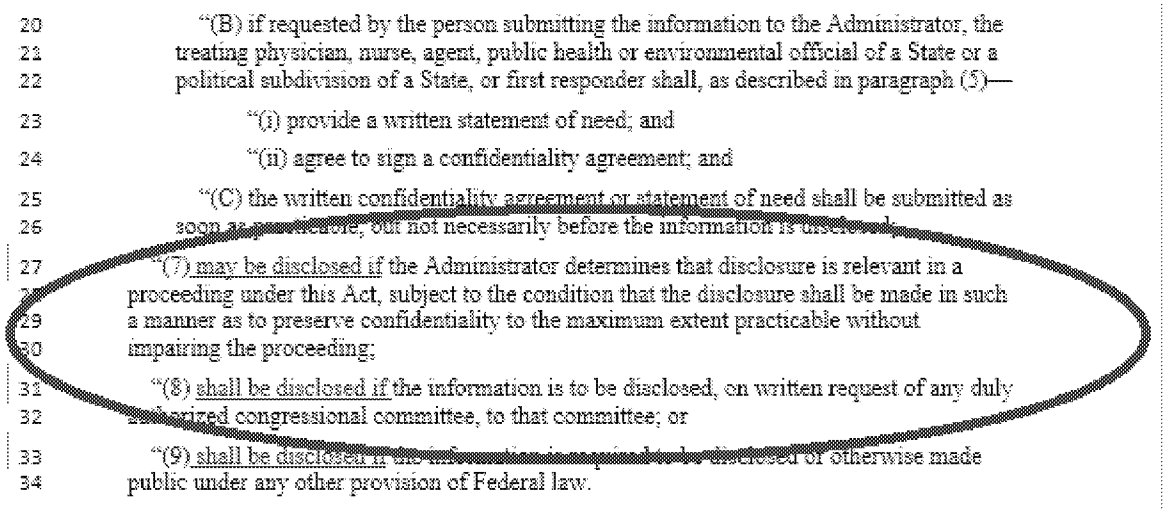
"(6) shall be disclosed if in the event of an emergency, a treating physician, nurse, agent of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder (including any individual duly authorized by a Federal agency, State, or political subdivision of a State who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) requests the information, subject to the conditions that—

"(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable basis to suspect that—

"(i) a medical or public health or environmental emergency exists;

"(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

"(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred;



"(B) if requested by the person submitting the information to the Administrator, the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

"(i) provide a written statement of need; and

"(ii) agree to sign a confidentiality agreement; and

"(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed.

"(7) may be disclosed if the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure shall be made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding;

"(8) shall be disclosed if the information is to be disclosed, on written request of any duly authorized congressional committee, to that committee; or

"(9) shall be disclosed if the information is required to be disclosed or otherwise made public under any other provision of Federal law.

From: Karakitsos, Dimitri (EPW)
Sent: Friday, April 24, 2015 12:04 PM
To: Black, Jonathan (Tom Udall); Wallace, Andrew (Tom Udall)

Under existing law there is a series of places where CBI "shall" and "may" be disclosed. As far as we know there have been no identified problems with where information "may" be disclosed – the very minor tweak in the bill changes one of the "shall" to conform with an existing law "may" and that is "may be disclosed when relevant in any proceeding under this Act, except that disclosure in such a proceeding shall be made in such a manner as to preserve confidentiality to the extent practicable without impairing the proceeding"

Exact same language, just conforming the "may" with existing law.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/24/2015 3:24:52 PM
To: 'Deveny, Adrian (Merkley)' [Adrian_Deveny@merkley.senate.gov]
Subject: RE: Sen. Merkley TSCA TA on Unreasonable risk

Adrian,
Thanks for the followup request. We will get you a response. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Deveny, Adrian (Merkley) [mailto:Adrian_Deveny@merkley.senate.gov]
Sent: Friday, April 24, 2015 11:21 AM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Merkley TSCA TA on Prioritization

Could EPA some TA on a potential definition of what "unreasonable risk" is not: ie no consideration of costs or non-risk factors.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, April 22, 2015 2:38 PM
To: Deveny, Adrian (Merkley)
Subject: Sen. Merkley TSCA TA on Prioritization

Adrian,
Please see the attached technical assistance in response to your request. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Deveny, Adrian (Merkley) [mailto:Adrian_Deveny@merkley.senate.gov]
Sent: Tuesday, April 21, 2015 6:03 PM
To: Kaiser, Sven-Erik; Vaught, Laura
Subject: Technical assistance

Just to add to your growing pile of TA on TSCA, I was hoping you could help me on Sec 4A Prioritization Screening, (c)(3)(A), allowing for 15-20% of high priority chemicals to be on the "additional priority" track. Could you provide me some language that would help to clarify that if EPA completes safety determinations more rapidly on these "additional priority" chemicals than "high priority" chemicals, that the "additional priority" list wouldn't repopulate more rapidly than the "high priority" list, thus causing over time the cumulative number of "additional priority" chemicals to exceed

20% of the cumulative number of "high priority" chemicals. And specifically, is it enough to just add the word cumulative, below, or would we need to make changes to the repopulation language?

"(3) LIMITATIONS.—In considering whether to grant a request submitted under paragraph (1), the Administrator shall ensure that—

"(A) if a sufficient number of additional priority requests meet the requirements of paragraph (1), not less than 15 percent, and not more than 20 percent, of the total cumulative number of substances designated to undergo safety assessments and safety determinations under this section are substances designated under the process and criteria pursuant to paragraph (1); and

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/24/2015 1:42:31 PM
To: 'Albritton, Jason (EPW)' [Jason_Albritton@epw.senate.gov]; 'bettina_poirier@epw.senate.gov' [bettina_poirier@epw.senate.gov]; Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: For Call at 9:30
Attachments: Boxer.TSCA TA on Chairmans Mark.docx

Resend

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

-----Original Message-----
From: Kaiser, Sven-Erik
Sent: Friday, April 24, 2015 9:28 AM
To: Vaught, Laura; Poirier, Bettina (EPW)
Cc: Albritton, Jason (EPW); Freedhoff, Michal (EPW)
Subject: RE: Call at 9:30

Call number is Ex. 6 - Personal Privacy, code Ex. 6 - Personal Privacy see attached doc with list of issues

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

-----Original Message-----
From: Vaught, Laura
Sent: Friday, April 24, 2015 9:21 AM
To: Poirier, Bettina (EPW)
Cc: Albritton, Jason (EPW); Freedhoff, Michal (EPW); Kaiser, Sven-Erik
Subject: Re: Call at 9:30

I am looping Sven for info on 9:30 technical call.

I can't join at 9:30, but Bettina let's plan on a smaller group of us connecting once you talk to the technical folks. I should be back around at 10:15.

Sent from my iPhone

> On Apr 24, 2015, at 9:17 AM, Poirier, Bettina (EPW) <Bettina_Poirier@epw.senate.gov> wrote:
>
> Just planning logistics of 9:30 call, jason and michal best numbers? Or epa, call in? I'm home sick and can call in or be added to chain.
>
> Sent from my iPad

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the4 agency or the administration on the bill, the draft language and comments.

***

§ 4(d)(4) Tiered Testing . . .

** 6 "(D) ADVANCED TESTING WITHOUT SCREENING.—The Administrator may require more advanced testing without conducting screening-level testing when other information available to the Administrator justifies the advanced testing, pursuant to guidance developed by the Administrator under this section.

This text refers to guidance "under this section." However, the section was just moved from § 3A to § 4. The cross-reference needs to be fixed, to reference guidance under section 3A.

***

§4A(a)(2) "(2) INITIAL LIST OF HIGH- AND LOW-PRIORITY SUBSTANCES.—

"(iii) PERSISTENCE AND BIOACCUMULATION.—In developing the initial list and in identifying additional high-priority substances, the Administrator shall give preference to chemical substances scored as high for persistence and bioaccumulation in the October 2014 TSCA Work Plan and subsequent updates.

The initial list includes both high- and low-priority substances. It should be clarified that the preference is "In developing the initial list of high-priority substances . . ."

***

§4A(a)(2) "(2) INITIAL LIST OF HIGH- AND LOW-PRIORITY SUBSTANCES.—

"(C) ADDITIONAL CHEMICAL REVIEWS.—The Administrator ~~shall—~~ **shall, as soon as practicable—**

"(i) 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 20 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 20 low-priority substances have been designated; and

"(ii) ~~as soon as practicable and not later than~~ 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 25 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to

ensure that at least a total of 25 low-priority substances have been designated.

Did you intend to drop "and not later than", in moving the text from (ii) to the intro to (C)? Without this text, it is not clear if this means within [3 or 5] years, as soon as practicable after the passage of [3 or 5] years, or as soon as practicable but not later than [3 or 5] years.

***

§4A(c) Additional Priorities for Safety Assessments and Determinations.—

"(1) IN GENERAL.—The prioritization screening process developed under subsection (a) shall—

"(A) include a process by which a manufacturer or processor of an active chemical substance that has not been designated a high-priority substance~~, or that has not been subject to~~ or is not in the process of a prioritization screening by the Administrator, may request that the Administrator designate the substance **as an additional priority** for a safety assessment and safety determination, subject to the payment of fees pursuant to section 26(b)(3)(E);

EPA assumes that the drafters don't intend for it to be possible to designate an already high-priority chemical substance as an Additional Priority Chemical Substance. Given that, "or is not in the process" should be changed to "and is not in the process." Otherwise, a high-priority chemical substance would qualify as an Additional Priority Chemical Substance, since it is not "in the process of a prioritization screening"

***

§ 5(d)(4) Restrictions.—

"(D) MITIGATION.—In selecting among prohibitions and restrictions to address an identified potential risk, the Administrator shall apply prohibitions or restrictions to articles on the basis of a chemical substance or mixture contained in the article only to the extent necessary to mitigate the identified potential risk.

§ 6(d)(2) Scope.—

"(II) in selecting among prohibitions and restrictions to address an identified risk, apply prohibitions or restrictions to articles on the basis of a chemical substance or

mixture contained in the article only to the extent necessary to mitigate the identified risk.

Similar issue in both provisions. The general risk management standard in § 6(d)(1) is what is "necessary to ensure that the chemical substance meets the safety standard. The phrase in § 6(d)(2)"necessary to mitigate the identified risk," could suggest that a lesser safety standard applies to a chemical substance in an article.

Similarly, the title of § 5(d)(4)(D), and the language "necessary to mitigate," could suggest that a lesser standard than "determine that the relevant chemical substance or significant new use is likely to meet the safety standard"(§ 5(d)3)) applies to new chemical substances in an article (e.g., new chemical substances in an imported article).

Finally, note that the basis for the risk management is whether the risk of the chemical substance meets the safety standard (or is likely to meet the safety standard, in the case of a new chemical). Introducing mixtures into the drafting here confuses the issue of the risk management standard, since there is no statutory basis to develop a risk assessment for a mixture, just for a chemical substance in a mixture. Striking "mixture" from the drafting allows the safety standard to be clearly articulated, and has no effect on the scope of EPA's authority.

Suggested fix:

*"(D) ~~MITIGATION~~.**Articles**—In selecting among prohibitions and restrictions to address an identified potential risk, the Administrator shall apply prohibitions or restrictions to articles on the basis of a chemical substance ~~or mixture~~ contained in the article only to the extent necessary to **determine that the chemical substance is likely to meet the safety standard** ~~mitigate the identified potential risk~~.*

*"(II) in selecting among prohibitions and restrictions to address an identified risk, apply prohibitions or restrictions to articles on the basis of a chemical substance ~~or mixture~~ contained in the article only to the extent necessary to **ensure that the chemical substance meets the safety standard** ~~mitigate the identified risk~~.*

***

§ 13 Entry into customs territory of the United States

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the4 agency or the administration on the bill, the draft language and comments.

There is a conforming change that still needs to be made to § 13, even if no substantive amendment to the section is intended.

> *TSCA 13(a)(1)(B) "it is offered for entry in violation of section 2604 of this title, 2605 of this title, or subchapter IV of this title, a rule or order under 2604 of this title, 2605 of this title, or subchapter IV of this title, or an order issued in a civil action brought under ~~section 2604 of this title,~~ 2606 of this title or subchapter IV of this chapter."*

Under current TSCA, it could sometimes be necessary for EPA to obtain a § 5 order from a federal judge, by filing a civil action. That provision has been deleted from § 5, and so it should not be mentioned in § 13.

***

§ 18(d)(1)

> "(C) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal~~, unless the action taken by the State or political subdivision of a State—~~ **except to the extent that the action—**

§ 18(d)(2)

> "(C) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal~~, unless the action taken by the State or political subdivision of a State—~~ **except to the extent that the action—**

Identical issue in both provisions. It remains unclear whether a state's waste transport and waste storage requirements would qualify for an exemption under 18(d)(1)(C) and 18(d)(2)(C). This remaining ambiguity could be resolved by substituting "waste management" for "waste treatment or disposal."

***

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the4 agency or the administration on the bill, the draft language and comments.

§ 18(f) State Waivers

"(7) JUDICIAL REVIEW OF PRIORITIZATION SCREENING DECISION.—Not later than 60 days after the date on which the Administrator makes a decision on a recommendation made under section 4A(b)(4) 4A(a)(4)(A) to designate a chemical substance as a low priority pursuant to section 4A(b)(4), the Governor of a State or a State agency with responsibility for protecting health and the environment that submitted the recommendation under section 4A(a)(4)(A), as applicable, may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit, which shall have exclusive jurisdiction over the determination.

This text is ambiguous about whether "as a low priority" refers to EPA's decision to designate or the State's recommendation to designate. Depending on how you resolve the ambiguity, this paragraph is either:

1. *A provision for the state to sue EPA when it asks for low and EPA gives the chemical a high; or*
2. *A provision for the state to sue EPA when it asks for a high and EPA gives the chemical a low*

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/24/2015 1:27:37 PM
To: Vaught, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c30920bcb6214a91b7e3c1e7810c63e1-Vaught, Laura]; Poirier, Bettina (EPW) [Bettina_Poirier@epw.senate.gov]
CC: Albritton, Jason (EPW) [Jason_Albritton@epw.senate.gov]; Freedhoff, Michal (EPW) [Michal_Freedhoff@epw.senate.gov]
Subject: RE: Call at 9:30
Attachments: Boxer.TSCA TA on Chairmans Mark.docx

Call number is Ex. 6 - Personal Privacy, code Ex. 6 - Personal Privacy see attached doc with list of issues

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

-----Original Message-----
From: Vaught, Laura
Sent: Friday, April 24, 2015 9:21 AM
To: Poirier, Bettina (EPW)
Cc: Albritton, Jason (EPW); Freedhoff, Michal (EPW); Kaiser, Sven-Erik
Subject: Re: Call at 9:30

I am looping Sven for info on 9:30 technical call.

I can't join at 9:30, but Bettina let's plan on a smaller group of us connecting once you talk to the technical folks. I should be back around at 10:15.

Sent from my iPhone

> On Apr 24, 2015, at 9:17 AM, Poirier, Bettina (EPW) <Bettina_Poirier@epw.senate.gov> wrote:
>
> Just planning logistics of 9:30 call, jason and michal best numbers? Or epa, call in? I'm home sick and can call in or be added to chain.
>
> Sent from my iPad

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/23/2015 9:20:42 PM
To: Michal Freedhoff [Michal_Freedhoff@markey.senate.gov]; jason_albritton@epw.senate.gov
Subject: Fwd: Sen. Markey TSCA TA request on throughput

Michal,

In response to your request, below is technical assistance responding to questions on throughput. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

To: "Vaught, Laura" <Vaught.Laura@epa.gov>
Subject: more TA requested

Hi Laura

We drafted up an amendment to increase throughput and fees such that the 1,000 chemicals most in need of assessment are completed within 25 years. Can you please provide TA? And generally, would you agree that it is possible to ramp up over time because it is likely the first assessments that will be the more complicated/lengthy?

Response: While it is likely that we will be able to ramp up the pace of assessments over time, the pace will be contingent on two factors. We anticipate that the prioritization process for high-priority substances would result in those assessments prioritized later in the process to move more quickly.

However, to complete this level of assessment in 25 years, there would need to significant breakthroughs in computational toxicology technologies currently under development. These technologies could have the potential to markedly increase throughput although EPA cannot predict, at present, when those technologies might become available for this purpose.

Thanks

Michal

On page 33, line 17, strike insert "as soon as practicable, but not later than" before "3 years".

On page 33, line 21, strike "20" and insert "40".

On page 34, line 2, strike "and".

On page 34, line 8, strike "25" and insert "100".

On page 34, line 14, strike the period and insert a semicolon.

On page 34, between lines 14 and 15, insert the following:

> (iii) as soon as practicable, but not later than 10 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 300 high-priority substances have undergone or are undergoing the process established in section 6(a); and
>
> (iv) as soon as practicable, but not later than 25 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 1,000 high-priority substances have undergone or are undergoing the process established in section 6(a).

On page 161, line 15, insert "clauses (i), (ii), and (iii) of" after "identified in".

On page 161, line 16, strike ", not to exceed $18,000,000" and insert "and 75 percent of the costs of conducting the activities identified in clauses (iv) and (v) of paragraph (2)(A)".

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/23/2015 9:07:41 PM
To: Michal Freedhoff [Michal_Freedhoff@markey.senate.gov]; jason_albritton@epw.senate.gov
Subject: Sen. Markey TSCA TA on unreasonable risk
Attachments: TA regarding Markey draft Unreasonable Risk definition.docx; ATT00001.htm

The attached TA responds to your request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: Vaught, Laura [mailto:Vaught.Laura@epa.gov]
Sent: Wednesday, April 22, 2015 5:22 PM
To: Freedhoff, Michal (Markey)
Cc: Poirier, Bettina (EPW)
Subject: Re: TA request - unreasonable risk

Got it. Will get it to team.

Sent from my iPhone

On Apr 22, 2015, at 5:17 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Laura

Can you guys take a look at this alternative definition of unreasonable risk for both our bosses? Drawn in part from SDWA.

Thanks

Michal

"(17) UNREASONABLE RISK. - The term 'unreasonable risk' means that the Administrator has found (i) that the chemical substance may have an adverse effect on human health (including on infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations) or the environment and (ii) that restrictions on such chemical substance using the best available technology and management practices to meaningfully reduce human health or ecological risk have not been required.

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations

Office of Senator Edward J. Markey

218 Russell Senate Office Building

Washington, DC 20510

202-224-2742

Connect with Senator Markey

<image001.png><image002.png><image003.png><image004.jpg>

TA regarding Markey draft Unreasonable Risk definition

Here's the draft text we received:

"(17) UNREASONABLE RISK. - The term 'unreasonable risk' means that the Administrator has found (i) that the chemical substance may have an adverse effect on human health (including on infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations) or the environment and (ii) that restrictions on such chemical substance using the best available technology and management practices to meaningfully reduce human health or ecological risk have not been required."

Here is our TA:

1. Part (i) of the test appears to be, or could be interpreted as, hazard-based, rather than risk-based. This interpretation would be reinforced by the fact that part (i) is adapted from the first part of a 3-part test in SDWA section 300g-1(b)(1)(A) to determine whether EPA must establish an MCL and MCLG for a contaminant. This provision of SDWA is strictly hazard-based; the other two parts of the SDWA test ~~of which~~ include elements of exposure.
2. Part (ii) of the test would require EPA to affirmatively demonstrate that the specified levels of control have not been required. This would impose an analytic burden on EPA – and create a corresponding litigation hook for the regulated community – to demonstrate that "restrictions. . . using the best available technology and management practices to meaningfully reduce impacts" have not been required, by EPA or another federal or state regulator, or a combination of regulators. The meaning of that phrase would most likely be litigated.
3. In addition, part (ii) creates some internal tension in the bill.
    a. Part (ii) appears to be principally a technology-based test ("best available technology"). The term "unreasonable risk" appears in the bill only in the definition of "safety standard". The safety standard requires that EPA determine whether there is unreasonable risk "without taking into consideration cost or other nonrisk factors". However, the technology-based consideration in draft part (ii) seems to be a nonrisk factor, at least in part.
    b. Also, the safety standard requires EPA to find that a chemical will not present unreasonable risk of injury to any identified potentially exposed populations. It is not clear how this requirement would interact with the "unreasonable risk" definition – e.g., would the best available technology determination have to be made with respect to individual potentially exposed populations?

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/22/2015 10:08:32 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: Udall TSCA TA Request on Asbestos
Attachments: Udall.TSCA TA.Asbestos.docx

Jonathan,
Please see attached TA that responds to your requests. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.
Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Tuesday, April 21, 2015 12:21 PM
To: Kaiser, Sven-Erik
Subject: RE: SEPW TSCA TA Request on Asbestos

Also… here is how asbestos is defined in OSHA:

Asbestos includes chrysotile, amosite, crocidolite, tremolite asbestos, anthophyllite asbestos, actinolite asbestos, and any of these minerals that have been chemically treated and/or altered.

Asbestos-containing material (ACM) means any material containing more than 1% asbestos.

I assume EPA isn't reviewing ACM.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, April 21, 2015 8:55 AM
To: Black, Jonathan (Tom Udall)
Subject: RE: SEPW TSCA TA Request on Asbestos

Jonathan,
I will ask folks to add the additional requested information. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Tuesday, April 21, 2015 7:46 AM
To: Kaiser, Sven-Erik
Subject: Re: SEPW TSCA TA Request on Asbestos

Thanks. Can you also (in addition) add another provision on top of that to ensure that existing asbestos safety information would be included and that new information could be added? We have a provision that says epa can make use of existing saftey information already.

And also disallow epa from any extensions under the deadlines.

Let me know if you have any questions.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, April 20, 2015 04:55 PM
To: Black, Jonathan (Tom Udall)
Subject: SEPW TSCA TA Request on Asbestos

Jonathan,
Thank you for the TA request. I'll let you know if any questions. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, April 20, 2015 4:41 PM
To: Kaiser, Sven-Erik
Cc: Jones, Jim
Subject: Asbestos...

We have more work for you!

Sen. Boxer's bill includes expedited action for "all-forms" of asbestos. (See below).

Can EPA provide T.A. drafting assistance to make asbestos -- as it appears on the 2014 TSCA Work Plan -- a high priority substance in S.697?

Also, what does EPA mean in the Work Plan by saying "asbestos-like fibers"?

7	Asbestos & Asbestos-like Fibers	Added 2012	Known human carcinogens Acute and chronic toxicity from inhalation exposures	3	Widely used in consumer products Present in indoor environments	3	High environmental persistence Low bioaccumulation potential

S.725 Boxer-Markey Language:

`(l) Asbestos-

`(1) LISTING- The Administrator shall include all forms of asbestos as 1 high-priority chemical substance under section 4A(a)(2) in accordance with section 4A(a)(4).

`(2) SCHEDULE- Notwithstanding paragraphs (3), (4) and (5) of subsection (a), the Administrator shall--

`(A) complete a safety assessment and safety determination of all forms of asbestos not later than 2 years after the date of enactment of the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act; and

`(B) promulgate a final rule not later than 3 years after the date of enactment of that Act.'.

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Incoming Question

What does EPA mean when it refers to "asbestos-like fibers"?

EPA Response:

When included in the TSCA Work Plan, asbestos and asbestos-like fibers were intended to include the six asbestiform minerals identified in Title II of TSCA:

- Chrysotile (serpentine mineral)
- Actinolite (amphibole mineral)
- Amosite (cummingtonite-grünerite) (an amphibole mineral)
- Anthophyllite (amphibole mineral)
- Crocidolite (riebeckite)(amphibole mineral)
- Tremolite (amphibole mineral)

In addition, at the time the Work Plan was developed, EPA was aware of evidence that other asbestos-like fibers have caused disease similar to the minerals identified originally in TSCA:

- Winchite and richterite from Libby, MT
- Ferro-actinolite from the Mesabi Range in MN
- Fluoroedenite from Biancavilla, Italy

Technical Assistance on Drafting (Relative to the Version 3.1 Baseline)

"SEC. 4A. PRIORITIZATION SCREENING.

"(a) Establishment and List of Substances.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish, by rule, a risk-based screening process and explicit criteria for identifying existing chemical substances that are—

"(A) a high priority for a safety assessment and safety determination under section 6 (referred to in this Act as 'high-priority substances'); and

"(B) a low priority for a safety assessment and safety determination (referred to in this Act as 'low-priority substances').

"(2) INITIAL LIST OF HIGH- AND LOW-PRIORITY SUBSTANCES.—

"(A) IN GENERAL.—Before the date of promulgation of the rule under paragraph (1) and not later than 180 days after the date of enactment of this section, the Administrator—

"(i) shall take into consideration and publish an initial list of high-priority

substances and low-priority substances; and

"(ii) pursuant to section 6(b), may initiate or continue safety assessments and safety determinations for those high-priority substances.

"(B) REQUIREMENTS.—

"(i) IN GENERAL.—The initial list of chemical substances shall contain at least 10 high-priority substances, at least 5 of which are drawn from the list of chemical substances identified by the Administrator in the October, 2014 TSCA Work Plan and subsequent updates, and at least 10 low-priority substances.

"(ii) SUBSEQUENTLY IDENTIFIED SUBSTANCES.—Insofar as possible, at least 50 percent of all substances subsequently identified by the Administrator as high-priority substances shall be drawn from the list of chemical substances identified by the Administrator in the October, 2014 TSCA Work Plan and subsequent updates, until all Work Plan chemicals have been designated under this subsection.

(iii) Persistence and Bioaccumulation.—In developing the initial list and in identifying additional high priority substances, the Administrator shall give preference to chemical substances scored as high for persistence and bioaccumulation in the October, 2014 TSCA Work Plan and subsequent updates.

(iv) The initial list of chemical substances shall contain asbestos as a high-priority substance.

"SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.";

(2) by redesignating subsections (e) and (f) as subsections (g) and (h), respectively;

(3) by striking subsections (a) through (d) and inserting the following:

"(a) In General.—The Administrator—

"(1) shall conduct a safety assessment and make a safety determination of each high-priority substance in accordance with subsections (b) and (c);

"(2) shall, as soon as practicable and not later than 6 months after the date on which a chemical substance is designated as a high-priority substance, define the scope of the safety assessment and safety determination to be conducted pursuant to this section, including the hazards, exposures, conditions of use, and potentially exposed or susceptible populations that the Administrator expects to consider;

"(3) as appropriate based on the results of a safety determination, shall establish restrictions pursuant to subsection (d);

"(4) shall complete a safety assessment and safety determination not later than 3 years after the date on which a chemical substance is designated as a high-priority substance;

"(5) shall promulgate a final rule pursuant to subsection (d) by not later than 2 years after the date on which the safety determination is completed; and

"(6) may extend any deadline under this subsection, **except a deadline with respect to asbestos**, for a reasonable period of time after an adequate public justification, subject to the condition that the aggregate length of all extensions of deadlines under paragraphs (4) and (5) and any deferral under subsection (c)(2) does not exceed 2 years.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/22/2015 6:38:01 PM
To: 'Deveny, Adrian (Merkley)' [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Merkley TSCA TA on Prioritization
Attachments: Merkley.TSCA TA.Prioritization.docx

Adrian,
Please see the attached technical assistance in response to your request. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Deveny, Adrian (Merkley) [mailto:Adrian_Deveny@merkley.senate.gov]
Sent: Tuesday, April 21, 2015 6:03 PM
To: Kaiser, Sven-Erik; Vaught, Laura
Subject: Technical assistance

Just to add to your growing pile of TA on TSCA, I was hoping you could help me on Sec 4A Prioritization Screening, (c)(3)(A), allowing for 15-20% of high priority chemicals to be on the "additional priority" track. Could you provide me some language that would help to clarify that if EPA completes safety determinations more rapidly on these "additional priority" chemicals than "high priority" chemicals, that the "additional priority" list wouldn't repopulate more rapidly than the "high priority" list, thus causing over time the cumulative number of "additional priority" chemicals to exceed 20% of the cumulative number of "high priority" chemicals. And specifically, is it enough to just add the word cumulative, below, or would we need to make changes to the repopulation language?

"(3) LIMITATIONS.—In considering whether to grant a request submitted under paragraph (1), the Administrator shall ensure that—

"(A) if a sufficient number of additional priority requests meet the requirements of paragraph (1), not less than 15 percent, and not more than 20 percent, of the total cumulative number of substances designated to undergo safety assessments and safety determinations under this section are substances designated under the process and criteria pursuant to paragraph (1); and

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Baseline = text offered in Version 3.1 response to Senators Booker, Merkley, and Whitehouse

§4A(c) …

"(3) LIMITATIONS.—In considering whether to grant a request submitted under paragraph (1), the Administrator shall ensure that—

"(A) if a sufficient number of additional priority requests meet the requirements of paragraph (1), not less than 15 percent, and not more than 20 percent, of the **cumulative** total number of substances **that have been** designated to undergo safety assessments and safety determinations under this section are substances designated under the process and criteria pursuant to paragraph (1); and

"(B) the resources allocated to conducting safety assessments and safety determinations for additional priorities designated under this subsection are proportionate to the **current** number of such substances relative to the total number of substances **that are currently** designated to undergo safety assessments and safety determinations under this section.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/22/2015 4:15:39 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: RE: SEPW TSCA TA Request on Asbestos

Jonathan, I expect we'll have something in the next couple of hours. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Wednesday, April 22, 2015 12:03 PM
To: Kaiser, Sven-Erik
Subject: RE: SEPW TSCA TA Request on Asbestos

Any updates on asbestos?

:)

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, April 21, 2015 12:29 PM
To: Black, Jonathan (Tom Udall)
Subject: RE: SEPW TSCA TA Request on Asbestos

Jonathan,
Thanks for the additional information. I will forward that to folks working on the technical assistance. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

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To: Kaiser, Sven-Erik
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To: Black, Jonathan (Tom Udall)
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U.S. EPA
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Washington, DC 20460
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And also disallow epa from any extensions under the deadlines.

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To: Black, Jonathan (Tom Udall)
Subject: SEPW TSCA TA Request on Asbestos

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Sven

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Sent: Monday, April 20, 2015 4:41 PM
To: Kaiser, Sven-Erik
Cc: Jones, Jim
Subject: Asbestos...

We have more work for you!

Sen. Boxer's bill includes expedited action for "all-forms" of asbestos. (See below).

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`(B) promulgate a final rule not later than 3 years after the date of enactment of that Act.'.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/21/2015 10:08:26 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]; Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
Subject: RE: SEPW TA on Q2- preemption and other federal laws
Attachments: SEPW.TSCA TA.Preemption Exceptions for Certain State Environmental Requirements.docx

Please see attached and let me know if any followup questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

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"(2) NO PREEMPTION OF STATE STATUTES AND ADMINISTRATIVE ACTIONS.—Nothing in this Act, nor any amendment made by this Act, nor any rule, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall affect the right of a State or a political subdivision of a State to adopt or enforce any rule, standard of performance, safety determination, scientific assessment, or any protection for public health or the environment that—

"(A) is adopted **or authorized** under the authority of~~, or authorized to comply with,~~ any other Federal law **or adopted to satisfy or obtain authorization or approval under any** other Federal law;

"(B) . . .

"(C) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal, ~~unless the action taken by the State or political subdivision of a State—~~ **except to the extent that the action—**

Commented [A1]: Consider also broadening this to "waste management" if the intent is to exempt state waste storage and transport rules from preemption.

"(i) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

"(ii)(I) **addresses the same hazards and exposures, with respect to the same conditions of use as** ~~is already required by a decision by the Administrator under section 5 or 6;~~

~~"(II) is taken to address a health or environmental concern that applies to the uses or conditions of use that~~ are included in the scope of a safety determination pursuant to section 6 ~~or the scope of a significant new use rule promulgated pursuant to section 5~~, but is inconsistent with the action of the Administrator; or

~~"(III)~~**"(II)** would cause a violation of the applicable action by the Administrator under section 5 or 6**; or**

"(D) . . .

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/21/2015 9:24:38 PM
To: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: SEPW TA on Q2- preemption and other federal laws

Dimitri,
Will have something for you tonight. Thanks,
Sven

On Apr 21, 2015, at 5:06 PM, "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov> wrote:

Sven any update on the TA?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Saturday, April 18, 2015 06:41 PM
To: Karakitsos, Dimitri (EPW)
Cc: Black, Jonathan (Tom Udall)
Subject: Re: SEPW TA on Q2- preemption and other federal laws

Dimitri,
Given your concerns, it seems like a call might be more helpful than more language. If you're interested let me know. Availability Monday or Tues? Thanks,
Sven

On Apr 18, 2015, at 12:41 PM, "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov> wrote:

Thanks again for all your help with TA and coordinating all this. I know you all have done a lot of work on this piece and I don't want to belabor the topic but I still have some serious concerns I wanted to share and see if anyone had good feedback or could further help with language or explain why I'm wrong. Hope I am not being too paranoid but it seems like the preemption section is being chipped away to protect some hypothetical problem that could be incredibly rare but open the door for some wider spread abuse of the system (see no low priority preemption, full judicial review of low priority chems, prop 65 carve out).

Again I am nervous that this type of language is leaving a potential giant loop hole for states to avoid preemption for a very limited number of situations where a real problem or conflict could ever arise. I have fairly rudimentary knowledge of the CAA so forgive me but as I understand it the feds set a standard or set of standards say for carbon dioxide - how often is a state (other than California who doesn't have to follow any rules) actually going to create a sip or program to meet fed requirements under state law that goes so far into detail that it will have to regulate a tsca approved use of a substance to meet that federal requirement under state law or delegated authority? In my rudimentary view not very often.

My point was if the state can credibly argue that it cannot maintain its delegated authority or meet a federal requirement without going after a tsca regulated chemical in a different or more stringent way then fine - allow it - but there should be some necessity to it. It should be necessary or at a minimum the most effective or efficient way for a state to meet its needs, not just a potential option of 100 others that the state has chosen possibly because they don't like the substance for other reasons or object to the tsca rule and its preemptive effect.

Simply put I am nervous under this language a state can easily justify ignoring the tsca preemption for a chemical

substance by saying their regulation is to protect water/air when they are not or may not be. Washington state's law for chemicals of concern and alternatives assessment is aimed at water quality, would that be able to avoid preemption under any of the language suggested? If some chemical substance is so damaging in a use to the ozone or its manufacture results in a large amount of voc or hap emissions/damaging discharges into water resources would EPA credibly ignore that even under tsca and say those emissions or discharges were totally fine for the environment?

I went from thinking this provision was a fair deal to being very concerned with it even being in the bill so any help in finding some middle ground or at least getting some further explanation here would be greatly appreciated.

My best suggestion at this point would be to go back to current law language since it has been interpreted by the Agency to work and there would be no need to codify the House report.

Thanks,

Dimitri

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 17, 2015 02:22 PM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW)
Subject: SEPW TA on Q2- preemption and other federal laws

Jonathan and Dimitri,

Attached please find technical assistance in response to your request. The attachment includes technical assistance on Q2 (preemption and other federal laws). The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/20/2015 6:05:47 PM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
Subject: Re: SEPW TA on Q2- preemption and other federal laws

The line is open - 866-299-3188, code 202-566-2753

On Apr 20, 2015, at 10:51 AM, "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov> wrote:

Jonathan, got the message regarding managing TA carefully. OGC and program will on the call at 2pm today.
Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, April 20, 2015 10:42 AM
To: Kaiser, Sven-Erik; Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TA on Q2- preemption and other federal laws

2pm works.
Here is the latest draft we have. This is STRICTLY confidential. I know you guys always do that. But we have heard some concerning stuff about other T.A. for other members getting discussed or mentioned with third parties, so I just want to reiterate.

Thanks.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, April 20, 2015 10:31 AM
To: Karakitsos, Dimitri (EPW)
Cc: Black, Jonathan (Tom Udall)
Subject: Re: SEPW TA on Q2- preemption and other federal laws

Dimitri,
2pm works. Please call 202-866-3188, code 202-566-2753. What version should we be working from, has the latest TA been incorporated into the draft? Thanks,
Sven

On Apr 18, 2015, at 8:41 PM, "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov> wrote:

Thanks Sven - Monday early afternoon work? Maybe 1 or 2pm?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Saturday, April 18, 2015 06:41 PM
To: Karakitsos, Dimitri (EPW)
Cc: Black, Jonathan (Tom Udall)
Subject: Re: SEPW TA on Q2- preemption and other federal laws

Dimitri,
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Thanks,

Dimitri

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 17, 2015 02:22 PM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW)
Subject: SEPW TA on Q2- preemption and other federal laws

Jonathan and Dimitri,

Attached please find technical assistance in response to your request. The attachment includes technical assistance on Q2 (preemption and other federal laws). The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/20/2015 3:23:55 PM
To: 'Wallace, Andrew (Tom Udall)' [Andrew_Wallace@tomudall.senate.gov]; 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]; Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
Subject: SEPW TSCA TA on injury v harm
Attachments: SEPW TSCA TA.injury v harm.docx

In response to your request, attached please find technical assistance on the definitional differences between "injury" and "harm." The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Sven

On Mar 6, 2015, at 3:02 PM, "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov> wrote:

When we met with EPA technical assistance, you demonstrated that there was inconsistency with the use of "injury" and "harm". You represented that "injury" is in current TSCA.

As a result, we conformed our legislation to be "injury".

Can you give us a quick response on what you believe "injury" to mean?

The term applies to health and the environment.

EPA comment on page 1.
"The bill uses "injury" numerous times, as does existing TSCA. Should be consistent, or have a reason for using injury in some places and harm in others."

Safety Standard from bill:

> "(16) SAFETY STANDARD.—The term 'safety standard' means a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of injury to health or the environment will result from exposure to a chemical substance under the conditions of use, including no unreasonable risk of injury to—
>
> "(A) the general population; or
>
> "(B) any potentially exposed or susceptible population that the Administrator has identified as relevant to the safety assessment and safety determination for a chemical substance.".

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Is there a difference in meaning between the words "injury" and "harm" in the context of environmental statutes?

EPA does not see a significant difference in meaning between "harm" and "injury". Indeed, in many cases the definitions of one term define it as the other.

Definitionally, the two words seem comparable. In ordinary usage, "injury" means: "damage of or to a person, property, reputation, or thing". American Heritage Dictionary Second College Edition. "Harm" means: "Physical or psychosocial injury or damage". Id. Merriam-Webster defines "injury" as: "harm or damage: an act or event that causes someone or something to no longer be fully healthy or in good condition." Merriam-Webster defines "harm" as: "physical or mental damage or injury: something that causes someone or something to be hurt, broken, made less valuable or successful, etc.".

In legal definitions, the meanings of the words overlap. Black's Law Dictionary, 9th ed., defines "injury" as: "The violation of another's legal right, for which the law provides a remedy; a wrong or injustice"; also: "any harm or damage". Black's defines "harm" as: "Injury, loss, damage; material or tangible detriment". In tort law, the two terms appear to be defined differently in some cases, which hold that "harm" denotes any personal loss or detriment, whereas "injury" involves an actionable invasion of a legally protected interest. Black's definition of "injury"; Restatement (Second) of Torts, section 7. Under these meanings, it appears that either word can be broader, depending on the context: an invasion of a right can be a legally cognizable injury even if there is no harm to a person or thing; on the other hand, there might be harms suffered that would not give rise to a cause of action because there is no protected right. Restatement (Second) or Torts, section 7.

It does not appear that differences in meaning recognized in the torts context, though, would have any bearing on the meaning of the terms under TSCA or other environmental laws. It is fairly clear that the term "injury" as used in TSCA does not refer to an invasion of a legally protected interest but rather to an insult caused by a chemical or mixture. Thus, "injury" in the current statute is most naturally read in the broader sense of "any harm or damage".

EPA queried staff attorneys working under all of the environmental laws, and no one identified any relevant authorities discussing differences in the meanings of the terms or identified any differences in meaning.

We are also not aware of arguments having been raised in implementation of TSCA that the term "injury" should be construed more narrowly than the broad meaning of "any harm or damage".

One last point is that taking the position that harm is broader than injury, the term predominantly used in current TSCA, and encompasses matters that injury does not, could impact future efforts under the existing statutory language if a revised statute were not adopted or one that perpetuated the use of the term injury were adopted.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/17/2015 6:22:53 PM
To: Jonathan Black [jonathan_black@tomudall.senate.gov]; Dimitri Karakitsos [dimitri_karakitsos@epw.senate.gov]
Subject: SEPW TA on Q2- preemption and other federal laws
Attachments: April 17 TA on Exemption from Preemption.docx; ATT00001.htm; Excerpt from TSCA Legislative History.pdf; ATT00002.htm

Jonathan and Dimitri,

Attached please find technical assistance in response to your request. The attachment includes technical assistance on Q2 (preemption and other federal laws). The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

Q2: Is it possible to delete/simplify "**or adopted for the purpose of satisfying or obtaining authorization or approval under** any other Federal law"?

Simply deleting this language would leave state actions such as the following subject to potential TSCA preemption, depending on a case-by-case analysis of whether they would be otherwise exempt from preemption under (d)(1)(C):

- State implementation plans, which are adopted under state law, and then submitted to EPA for approval under the Clean Air Act
- State water quality standards, which are adopted under state law, and then submitted to EPA for approval under the Clean Water Act.
- State effluent limitations, which are issued under state law in a manner intended to satisfy EPA requirements for operating an approved permitting program under the Clean Water Act.

This is an illustrative list, not a complete list.

The root of the difficulty in drafting this section is that existing TSCA is confusing in its use of the term "adopted under the authority of . . . Federal law." Under a plain reading of these words, state implementation plans, state water quality standards, and state effluent limitations would not be adopted under the authority of Federal law. These are all examples of the state operating under *its own* legal authorities, but subject to federal oversight and the backstop of potential EPA intervention under federal law. And yet the legislative history of current TSCA reflects a broader view of what it means to be operating "under the authority of . . . Federal law," so as to exempt such state actions from preemption. See H.R. Rep. No. 94-1341 at 54 (1976).

If your intent is to maintain the status quo exemption of these categories of state action from TSCA preemption, but the lengthier drafting approach suggested in prior technical assistance is simply too verbose, the following alternative approach to amending the bill would effectuate your intent:

(d) Exceptions.—

(1) . . .

"(A) is adopted under the authority of~~,~~ **the Clean Air Act** or ~~authorized to comply with~~, any other Federal law~~;~~**, with the scope of this exception to be construed consistent with H. R. Rep. No. 94-1341 at 54 (1976);**

Q3: Can you review the proposed draft changes to subsection (d)(1)(C) [mirrored in (d)(2)(C)] to ensure the intent of preserving actions (including even chemical restrictions) that states have taken or would take under state statutes to address different health/environmental concerns than those EPA has addressed under TSCA?

Further response (to supplement prior TA response of 4/15):

Unless the policy intent is that the preemption exemption would not be available for state requirements related to waste *storage* or waste *transport*, the following would be a helpful clarification of the scope of §18(d)(1)(C) and d(2)(C):

"related to water quality, air quality, or waste ~~treatment or disposal~~ **management** . . ."

article containing such substance or mixture shall be liable to be proceeded against for seizure and condemnation. Actions for such seizure and condemnation may be brought in any United States district court within the jurisdiction of which such substance, mixture, or article is found, and the proceedings shall conform as nearly as possible to proceedings in rem in admiralty.

SECTION 18, PREEMPTION

Section 18(a) provides generally that nothing in the bill shall effect the authority of a State or political subdivision to establish or continue in effect regulation of any chemical substance, mixture or article containing a chemical substance or mixture. However, except as otherwise provided, rules under section 5 and 6 shall preempt nonidentical State and local requirements respecting the same chemical substance, mixture, or article containing a substance or mixture, if the State or local requirement addresses the same risk to health or environment associated with the chemical substance, mixture, or article. Similarly, if the Administrator establishes a testing rule under section 4, no State or political subdivision may establish or continue in effect a testing rule for purposes similar to those for which the testing is required under section 4.

However, rules under section 6(a)(5) relating to disposal do not preempt any State or local requirements. Further, if a State or local requirement is adopted under the authority of the Clean Air Act or any other Federal law, the Federal rule shall not preempt the State or local requirement. Thus, for instance, State emission standards, effluent limitations, or other regulatory requirements adopted under the Clean Air Act or Federal Water Pollution Control Act would not be preempted by rules issued under this bill, even though the State or local requirement were more stringent. This would be the case if a State limitation, standard, or requirement were adopted, submitted, and approved as part of a State implementation plan required under Federal law. Similarly, the preemption would not apply to a State or local limitation, standard, or requirement if it were adopted under the State or local government's authority which is preserved by a provision of Federal law, such as a section 116 of the Clean Air Act or sections 1414(c) or 1424(c) of the Public Health Service Act (relating to safe drinking water).

The Committee recognizes the traditional role of the State and local governments in providing for the protection of their citizens. As a result in addition to the specific exemptions from the preemption provision, the Committee bill provides a means whereby a State or political subdivision may seek an exemption from the Federal preemption in order to provide a higher degree of protection for their citizens than that provided by regulations under this bill. Under subsection (b), the Administrator may by rule exempt from the preemption provisions a requirement of a State or political subdivision if three conditions are satisfied. First, compliance with the State or local requirement must not cause a violation of the applicable requirement under the bill. Second, the State or political subdivision requirement must provide a significantly higher degree of protection from the risk. Third, the State

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/17/2015 11:15:54 AM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
CC: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Vaught, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c30920bcb6214a91b7e3c1e7810c63e1-Vaught, Laura]; Distefano, Nichole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31d32a3a3a9e4591b5fdfc3eb96e8b78-Distefano,]
Subject: Re: SEPW TSCA TA Request

Checking

On Apr 17, 2015, at 7:13 AM, "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov> wrote:

Sven, we really need the remaining piece ASAP. We'd like to deliver an offer on Monday. Is it possible to get a response on that point today?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, April 15, 2015 4:53 PM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW); Vaught, Laura; Distefano, Nichole
Subject: SEPW TSCA TA Request

Jonathan and Dimitri,
Attached please find technical assistance in response to your request. The attachment includes technical assistance on all of the questions except Q2 (preemption and other federal laws). Q2 is still in progress. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Wednesday, April 15, 2015 11:56 AM
To: Kaiser, Sven-Erik; Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TSCA TA Request

Checking in. Any chance we can have this by 4pm today?

Thanks!
---jb

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 10, 2015 4:12 PM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TSCA TA Request

Jonathan and Dimitri,

Thanks for talking with us today about the technical assistance. We'll start on the request below and let you know if any questions. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Friday, April 10, 2015 4:05 PM
To: Kaiser, Sven-Erik; Karakitsos, Dimitri (EPW)
Cc: Black, Jonathan (Tom Udall)
Subject: RE: SEPW TSCA TA Request

Sven,

Thanks for the Technical Assistance Call today.

To follow-up, EPA has agreed to propose some language on "articles" that would codify existing practice on treatment of articles. We are hoping to see that language by Tuesday/Wednesday.

As well, we discussed exceptions for state statutes. We have a few questions that are keyed from the following draft text:

Q1: Would there be any effect from deleting 18(d)(1) if 18(d)(2) is retained?

Q2: Is it possible to delete/simplify "**or adopted for the purpose of satisfying or obtaining authorization or approval under** any other Federal law"?

Q3: Can you review the proposed draft changes to subsection (d)(1)(C) [mirrored in (d)(2)(C)] to ensure the intent of preserving actions (including even chemical restrictions) that states have taken or would take under state statutes to address different health/environmental concerns than those EPA has addressed under TSCA?

(d) Exceptions.—

"(1) IN ~~GENERAL.—SUBSECTIONS (A) AND (B)~~ **GENERAL.—Subsection (a)** shall not apply to a statute or administrative action of a State or a political subdivision of a State applicable to a specific chemical substance that—

"(A) is adopted **or authorized** under the authority of~~, or authorized to comply with,~~ **any other Federal law or adopted for the purpose of satisfying or obtaining authorization or approval under** any other Federal law;

"(B) implements a reporting, monitoring, or other information collection obligation for the chemical substance not otherwise required by the Administrator under this Act or required under any other Federal law; or

"(C) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal, ~~unless the action taken by the State or political subdivision of a State —~~ **except to the extent that the action—**

"(i) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

"(ii)(I) **addresses the same hazards ~~and~~ or exposures, with respect to the same conditions of use, as ~~is already required by a decision by the Administrator under section 5 or 6;~~**

~~"(II) is taken to address a health or environmental concern that applies to the uses or conditions of use that~~ are included in the scope of a safety determination pursuant to section 6 **~~or the scope of a significant new use rule promulgated pursuant to section 5~~**, but is inconsistent with the **~~action~~ determination** of the Administrator under section 6(c)(1)(A) or a rule promulgated by the Administrator under section 6(d); or

~~"(III)~~"(II) would cause a violation of the applicable action by the Administrator under section 5 or 6**; or**

"(2) NO PREEMPTION OF STATE STATUTES AND ADMINISTRATIVE ACTIONS.—Nothing in this Act, nor any amendment made by this Act, nor any rule, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall affect the right of a State or a political subdivision of a State to adopt or enforce any rule, standard of performance, safety determination, scientific assessment, or any protection for public health or the environment that—

"(A) is adopted **or authorized** under the authority of**~~, or authorized to comply with,~~ any other Federal law or adopted for the purpose of satisfying or obtaining authorization or approval under** any other Federal law;

"(B) implements a reporting, monitoring, **disclosure,** or other information ~~collection~~ obligation for the chemical substance not otherwise required by the Administrator under this Act or required under any other Federal law; ~~or~~

"(C) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal, ~~unless the action taken by the State or political subdivision of a State —~~ **except to the extent that the action—**

"(i) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

"(ii)(I) **addresses the same hazards ~~and~~ or exposures, with respect to the same conditions of use as ~~is already required by a decision by the Administrator under section 5 or 6;~~**

~~"(II) is taken to address a health or environmental concern that applies to the uses or conditions of use that~~ are included in the scope of a safety determination pursuant to section 6 **~~or the scope of a significant new use rule promulgated pursuant to section 5~~**, but is inconsistent with the ~~action~~ determination of the Administrator under section 6(c)(1)(A) or a rule promulgated by the Administrator under section 6(d);

~~"(III)~~"(II) would cause a violation of the applicable action by the Administrator under section 5 or 6**; or**

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Thursday, April 09, 2015 5:13 PM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall)
Subject: EPA TA

Sven,

Here are a few things we would greatly appreciate some EPA TA on. We may need to discuss some further so if a phone call would be helpful please just let me know and thanks in advance for the help. I am also happy to work with you to help facilitate a call between your folks and some interested parties on the articles language if you think that would help.

Dimitri

Articles

It was my understanding that under current TSCA if EPA were looking to regulate an article or articles the Agency would already have somewhat of a higher bar and do some level of extra analysis of finding there is an exposure to a chemical substance from an article or group of articles. I had a brief conversation that I interpreted as the Agency not being against some heightened review to determine when article specific regulations were necessary but clearly we understand the challenges and hurdles the language we have in the bill today seem to cause. Below are two proposals, one from an outside counsel which I don't think addresses all your concerns and one that we worked up to see what you all thought. It is important to us to have something on articles in the bill, striking is not much of an option so if you all can please review and provide guidance we would appreciate.

- <!--[if !supportLists]--><!--[endif]-->Proposed language – If the Administrator intends to prohibit or otherwise restrict an article, or a category of articles that perform similar functions and have similar patterns of exposure, on the basis of a chemical substance contained in that article or category, the Administrator shall have evidence of significant exposure to the chemical substance from such article or category.
- <!--[if !supportLists]--><!--[endif]-->Draft staff language - New 3A(h)(2)(C)(ii)(III): " when considering the regulation of an article, or a category of articles, in a rulemaking under section 6, clearly describe the exposure or exposures to the chemical substance determined by the Administrator to be associated with such articles or categories of articles."

Preemption

Waiver – in our State Waivers we have two separate provisions that require a showing of a "compelling state or local" condition or interest. Those provisions were not intended to mean that the state would have to show some different exposures or unique conditions to meet that requirement, it was simply that they had a genuine concern with the substance that led them to request the waiver. Is there some way to clarify?

Exceptions/No Preemption of State Statutes and Administrative Actions – these two provisions other than their intro paragraphs are identical. The request for clarification and TA comes from subsection A in both 1 and 2. I have concern that "for the purpose of satisfying or obtaining authorization or approval under any other federal law" is incredibly broad and could leave loop holes for states to regulate TSCA regulated chemical substances in ways inconsistent with EPA decisions under the law. If EPA for example (possibly not the most eloquent or well thought out example) found a product safe for use in an aerosol application yet a state banned it under their state law to comply with the CAA to reduce VOCs or some other air pollutant – maybe it is one option the state could take "for the purpose of satisfying or obtaining authorization or approval" but it may be one of a range of options – why should that be inconsistent with an EPA TSCA decision. I think at a minimum I would prefer language stating the state level restriction is "necessary" to satisfy or obtain authorization or approval rather than "for the purpose of."

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/16/2015 1:39:33 PM
To: 'Cohen, Jacqueline' [jackie.cohen@mail.house.gov]; Fowler, Jamie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b74e8771b8049e5bde0f26dc5b1de97-JFowler6]; Schmit, Ryan [Ryan.Schmit@mail.house.gov]
Subject: HEC TSCA Reform TA Request

Jacqueline,
How about 4:15 or 4:30 today for a call with Wendy and OGC? Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Cohen, Jacqueline [mailto:jackie.cohen@mail.house.gov]
Sent: Wednesday, April 15, 2015 6:18 PM
To: Kaiser, Sven-Erik; Fowler, Jamie
Cc: Schmit, Ryan
Subject: TA on a couple of possible changes

Hey guys,

We are trying to think through some language edits to address some of the problems Jim raised yesterday. These don't get at the minimums or the fee questions yet. Can we get TA on these, and whether they would address the raised concerns?

In Section 6(a) of TSCA, in the last line, strike "such risk" and insert "the risk identified pursuant to subsection (b), including identified risks to potentially exposed subpopulations."

On page 5 of the draft, lines 10-11, change "combination of hazard from and exposure to the chemical substance" to "hazard from, exposure to, or a combination of hazard from and exposure to the chemical substance"

On page 10, line 18, rewrite (B) to read:
"(B) in selecting among prohibitions and restrictions to address an identified risk, apply requirements under the rule that the Administrator determines, consistent with the information published under subparagraph (A), are cost effective."
Our intent with this change is to explicitly state that cost only matters in choosing among options that address the risk. An alternative would be to make a new (A) that says

"(A) Consider costs, including the reasonably ascertainable economic consequences of the rule … (the language on page 10, lines 12-17), but need not balance costs and benefits."

Thank you!

Jacqueline G. Cohen
Senior Counsel
Committee on Energy and Commerce, Democratic Staff
U.S. House of Representatives

jacqueline.cohen@mail.house.gov
202-225-4407

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/16/2015 1:05:21 PM
To: 'Cohen, Jacqueline' [jackie.cohen@mail.house.gov]; Fowler, Jamie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b74e8771b8049e5bde0f26dc5b1de97-JFowler6]; Schmit, Ryan [Ryan.Schmit@mail.house.gov]
Subject: HEC TSCA Reform TA Request

Jacqueline,
Thank you for the technical assistance request. I will circulate the request and get back to you about setting up a time to discuss. Please let me know if any additional questions. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Cohen, Jacqueline [mailto:jackie.cohen@mail.house.gov]
Sent: Wednesday, April 15, 2015 6:18 PM
To: Kaiser, Sven-Erik; Fowler, Jamie
Cc: Schmit, Ryan
Subject: TA on a couple of possible changes

Hey guys,

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Thank you!

Jacqueline G. Cohen
Senior Counsel
Committee on Energy and Commerce, Democratic Staff

U.S. House of Representatives
jacqueline.cohen@mail.house.gov
202-225-4407

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/15/2015 10:47:17 PM
To: Cohen, Jacqueline [jackie.cohen@mail.house.gov]
CC: Fowler, Jamie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b74e8771b8049e5bde0f26dc5b1de97-JFowler6]; Schmit, Ryan [Ryan.Schmit@mail.house.gov]
Subject: Re: TA on a couple of possible changes

Jacqueline,
Thank you for the technical assistance request. We'll be glad to review and get back to you with a response. What's your sense of timing? Thanks,
Sven

On Apr 15, 2015, at 6:18 PM, "Cohen, Jacqueline" <jackie.cohen@mail.house.gov> wrote:

Hey guys,

We are trying to think through some language edits to address some of the problems Jim raised yesterday. These don't get at the minimums or the fee questions yet. Can we get TA on these, and whether they would address the raised concerns?

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"(A) Consider costs, including the reasonably ascertainable economic consequences of the rule … (the language on page 10, lines 12-17), but need not balance costs and benefits."

Thank you!

Jacqueline G. Cohen
Senior Counsel
Committee on Energy and Commerce, Democratic Staff
U.S. House of Representatives
jacqueline.cohen@mail.house.gov
202-225-4407

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/15/2015 8:52:51 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]; Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Vaught, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c30920bcb6214a91b7e3c1e7810c63e1-Vaught, Laura]; Distefano, Nichole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31d32a3a3a9e4591b5fdfc3eb96e8b78-Distefano,]
Subject: SEPW TSCA TA Request
Attachments: SEPW TA on Articles and Preemption.4.15.15.docx

Jonathan and Dimitri,
Attached please find technical assistance in response to your request. The attachment includes technical assistance on all of the questions except Q2 (preemption and other federal laws). Q2 is still in progress. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Wednesday, April 15, 2015 11:56 AM
To: Kaiser, Sven-Erik; Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TSCA TA Request

Checking in. Any chance we can have this by 4pm today?

Thanks!
---jb

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 10, 2015 4:12 PM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TSCA TA Request

Jonathan and Dimitri,
Thanks for talking with us today about the technical assistance. We'll start on the request below and let you know if any questions. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Friday, April 10, 2015 4:05 PM
To: Kaiser, Sven-Erik; Karakitsos, Dimitri (EPW)
Cc: Black, Jonathan (Tom Udall)
Subject: RE: SEPW TSCA TA Request

Sven,

Thanks for the Technical Assistance Call today.

To follow-up, EPA has agreed to propose some language on "articles" that would codify existing practice on treatment of articles. We are hoping to see that language by Tuesday/Wednesday.

As well, we discussed exceptions for state statutes. We have a few questions that are keyed from the following draft text:

Q1: Would there be any effect from deleting 18(d)(1) if 18(d)(2) is retained?

Q2: Is it possible to delete/simplify "**or adopted for the purpose of satisfying or obtaining authorization or approval under** any other Federal law"?

Q3: Can you review the proposed draft changes to subsection (d)(1)(C) [mirrored in (d)(2)(C)] to ensure the intent of preserving actions (including even chemical restrictions) that states have taken or would take under state statutes to address different health/environmental concerns than those EPA has addressed under TSCA?

(d) Exceptions.—

"(1) IN ~~GENERAL.—SUBSECTIONS (A) AND (B)~~ **GENERAL.—Subsection (a)** shall not apply to a statute or administrative action of a State or a political subdivision of a State applicable to a specific chemical substance that—

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the ~~action~~ **determination** of the Administrator under section 6(c)(1)(A) or a rule promulgated by the Administrator under section 6(d); or

~~"(III)~~**"(II)** would cause a violation of the applicable action by the Administrator under section 5 or 6**; or**

"(2) NO PREEMPTION OF STATE STATUTES AND ADMINISTRATIVE ACTIONS.—Nothing in this Act, nor any amendment made by this Act, nor any rule, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall affect the right of a State or a political subdivision of a State to adopt or enforce any rule, standard of performance, safety determination, scientific assessment, or any protection for public health or the environment that—

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From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Thursday, April 09, 2015 5:13 PM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall)
Subject: EPA TA

Sven,

Here are a few things we would greatly appreciate some EPA TA on. We may need to discuss some further so if a phone call would be helpful please just let me know and thanks in advance for the help. I am also happy to work with you to help facilitate a call between your folks and some interested parties on the articles language if you think that would help.

Dimitri

Articles
It was my understanding that under current TSCA if EPA were looking to regulate an article or articles the Agency would already have somewhat of a higher bar and do some level of extra analysis of finding there is an exposure to a chemical

substance from an article or group of articles. I had a brief conversation that I interpreted as the Agency not being against some heightened review to determine when article specific regulations were necessary but clearly we understand the challenges and hurdles the language we have in the bill today seem to cause. Below are two proposals, one from an outside counsel which I don't think addresses all your concerns and one that we worked up to see what you all thought. It is important to us to have something on articles in the bill, striking is not much of an option so if you all can please review and provide guidance we would appreciate.

- Proposed language – If the Administrator intends to prohibit or otherwise restrict an article, or a category of articles that perform similar functions and have similar patterns of exposure, on the basis of a chemical substance contained in that article or category, the Administrator shall have evidence of significant exposure to the chemical substance from such article or category.
- Draft staff language - New 3A(h)(2)(C)(ii)(III): " when considering the regulation of an article, or a category of articles, in a rulemaking under section 6, clearly describe the exposure or exposures to the chemical substance determined by the Administrator to be associated with such articles or categories of articles."

Preemption

Waiver – in our State Waivers we have two separate provisions that require a showing of a "compelling state or local" condition or interest. Those provisions were not intended to mean that the state would have to show some different exposures or unique conditions to meet that requirement, it was simply that they had a genuine concern with the substance that led them to request the waiver. Is there some way to clarify?

Exceptions/No Preemption of State Statutes and Administrative Actions – these two provisions other than their intro paragraphs are identical. The request for clarification and TA comes from subsection A in both 1 and 2. I have concern that "for the purpose of satisfying or obtaining authorization or approval under any other federal law" is incredibly broad and could leave loop holes for states to regulate TSCA regulated chemical substances in ways inconsistent with EPA decisions under the law. If EPA for example (possibly not the most eloquent or well thought out example) found a product safe for use in an aerosol application yet a state banned it under their state law to comply with the CAA to reduce VOCs or some other air pollutant – maybe it is one option the state could take "for the purpose of satisfying or obtaining authorization or approval" but it may be one of a range of options – why should that be inconsistent with an EPA TSCA decision. I think at a minimum I would prefer language stating the state level restriction is "necessary" to satisfy or obtain authorization or approval rather than "for the purpose of."

This technical assistance is provided by EPA in response to a congressional request. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

To follow-up, EPA has agreed to propose some language on "articles" that would codify existing practice on treatment of articles. We are hoping to see that language by Tuesday/Wednesday.

Commented [A1]: Delete Section 3A(h)(3):

~~"(3) ARTICLES.—If the Administrator intends to prohibit or otherwise restrict an article on the basis of a chemical substance contained in that article, the Administrator shall have evidence of significant exposure to the chemical substance from such article.~~

Add Section 3A(h)(2)(C)(vii):

"(C) MINIMUM REQUIREMENTS.—At a minimum, the policies and procedures under this paragraph shall—
…

(vii) require that in any safety assessment or safety determination that attributes exposure to a chemical substance to the manufacture, processing, distribution in commerce, use or disposal of the chemical substance in an article or category of articles, the Administrator shall explain with particularity the basis for such attribution and the information supporting such attribution.

This technical assistance is provided by EPA in response to a congressional request. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

As well, we discussed exceptions for state statutes. We have a few questions that are keyed from the following draft text:

Q1: Would there be any effect from deleting 18(d)(1) if 18(d)(2) is retained?

Q2: Is it possible to delete/simplify "**or adopted for the purpose of satisfying or obtaining authorization or approval under** any other Federal law"?

Commented [A2]: The answer depends on whether 18(d)(1)(A)-(C) exactly matches 18(d)(2)(A)-(C). In the drafting below, there is not an exact match. However, there is an exact match in the introduced bill.

Assuming that there is an exact match in the provisions of (1)(A)-(C) and (2)(A)-(C), then deleting paragraph (1) would have no effect.

This is because paragraph (1) only limits the preemptive effect of subsections 18(a) and (b) [or just 18(a) as now revised?], while paragraph (2) limits the preemptive effect of the entire Act and rules and orders under the Act. The introductory language of paragraph (2) thus subsumes the introductory language of paragraph (1).

Commented [A3]: This request for TA is still under analysis.

This technical assistance is provided by EPA in response to a congressional request. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Q3: Can you review the proposed draft changes to subsection (d)(1)(C) [mirrored in (d)(2)(C)] to ensure the intent of preserving actions (including even chemical restrictions) that states have taken or would take under state statutes to address different health/environmental concerns than those EPA has addressed under TSCA?

(d) Exceptions.—

"(1) IN ~~GENERAL.—SUBSECTIONS (A) AND (B)~~ GENERAL.—**Subsection (a)** shall not apply to a statute or administrative action of a State or a political subdivision of a State applicable to a specific chemical substance that—

"(A) is adopted **or authorized** under the authority of~~, or authorized to comply with,~~ **any other Federal law or adopted for the purpose of satisfying or obtaining authorization or approval under** any other Federal law;

"(B) implements a reporting, monitoring, or other information collection obligation for the chemical substance not otherwise required by the Administrator under this Act or required under any other Federal law; ~~or~~

"(C) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal, ~~unless the action taken by the State or political subdivision of a State~~ — **except to the extent that the action—**

"(i) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

"(ii)(I) **addresses the same hazards and or exposures, with respect to the same conditions of use, as** ~~is already required by a decision by the Administrator under section 5 or 6;~~

~~"(II) is taken to address a health or environmental concern that applies to the uses or conditions of use that~~ are included in the scope of a safety determination pursuant to section 6 ~~or the scope of a significant new use rule promulgated pursuant to section 5,~~ but is inconsistent with the ~~action~~ **determination** of the Administrator under section 6(c)(1)(A) or a rule promulgated by the Administrator under section 6(d); or

~~"(III)~~"**(II)** would cause a violation of the applicable action by the Administrator under section 5 or 6; **or**

"(2) NO PREEMPTION OF STATE STATUTES AND ADMINISTRATIVE ACTIONS.—Nothing in this Act, nor any amendment made by this Act, nor any rule, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall affect the right of a State or a political subdivision of a State to adopt or enforce any rule, standard of performance, safety determination, scientific assessment, or any protection for public health or the environment that—

"(A) is adopted **or authorized** under the authority of~~, or authorized to comply with,~~ **any other Federal law or adopted for the purpose of satisfying or obtaining authorization or approval under** any other Federal law;

Commented [A4]: The most straightforward way to accomplish this objective would be to significantly shorten (C) to say what you want to say

– e.g.: "(C) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal to address different health or environmental concerns than those addressed by the Administrator under this Act."

We have pointed out possible issues in the changes you have suggested to (C), but we note more generally that the complex drafting of (C) to convey a relatively simple idea creates the potential for issues.

Commented [A5]: This change would be moot if (d)(1) is to be deleted in its entirety. If (d)(1) and (d)(2) are both retained, this seems inconsistent with the intent in (d)(2) that the exemptions under (A)-(C) across the board to all preemption under TSCA.

Also, this change does not seem consistent with your stated intention, since it would allow for preemption under 18(b) of state actions that address health or environmental concerns that EPA has not addressed.

Commented [A6]: Changing the "and" to an "or" would mean that a state law would be preempted, even if it addressed a hazard or exposure that was beyond the scope of the TSCA safety assessment. A partial nexus (e.g., overlap on the hazard alone or overlap on the exposure alone) would suffice to allow preemption.

Was that the intent?

Commented [A7]: This "or" should be deleted. § 18(d)(1) and (2) are not linked in the alternative.

Commented [A8]: We didn't develop TA on § 18(d)(2)(A)-(C), although we note that 18(d)(2)(A)-(C) doesn't exactly mirror 18(d)(1)(A)-(C).

"(B) implements a reporting, monitoring, **disclosure,** or other information ~~collection~~ obligation for the chemical substance not otherwise required by the Administrator under this Act or required under any other Federal law; ~~or~~

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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/15/2015 6:49:18 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
CC: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
Subject: RE: SEPW TSCA TA Request

Jonathan and Dimitri,
I expect to have something on articles for you shortly. Preemption raised additional issues and unfortunately will not be resolved today although we are working to get it to you as soon as possible. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Wednesday, April 15, 2015 2:47 PM
To: Kaiser, Sven-Erik
Cc: Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TSCA TA Request

Any intel to share? thanks

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, April 15, 2015 12:22 PM
To: Black, Jonathan (Tom Udall)
Cc: Karakitsos, Dimitri (EPW)
Subject: Re: SEPW TSCA TA Request

Checking , thanks

On Apr 15, 2015, at 11:56 AM, "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov> wrote:

Checking in. Any chance we can have this by 4pm today?

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From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Thursday, April 09, 2015 5:13 PM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall)
Subject: EPA TA

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Dimitri

Articles

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From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 11/20/2015 9:25:12 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on enzyme name
Attachments: Markey.TSCA TA. Enzyme Nomenclature.docx

Michal – attached please find technical assistance that responds to your questions on nomenclature. The TA responds to the second and third questions. The response to the first question on current use of the enzyme nomenclature system is still under development. Please let me know if any additional questions. Thanks, Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, November 06, 2015 2:18 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA Request on enzyme name

Yes - interested in following:

- does epa currently utilize this Enzyme nomenclature system, in same way it uses the soap one, portland cement systems etc. Is it appropriate to add this one to the list, if one has such a list in statute in the first place?
- can we soften the statutory text to say that epa shd maintain the nomenclature systems named unless epa by rule and following some named criteria replaces the named system w something else?
- can we figure out a section 5 process that may or may not be analogous to what the section 21 petition asked you to do that specifies a process by which someone can demonstrate that their chemical or feedstock is equivalent to something already on the inventory for purposes of determining whether they need to submit a pmn? Ideally, such a process would not allow someone to assert equivalence when none exists in a manner that erodes epa's current authority to require pmns when appropriate, but would provide a certain and specified process and timeframe for an applicant to be able to get the question answered.

Thank you

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik
Sent: Friday, November 6, 2015 1:43 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on enzyme name

Michal,
Thank you for sending the draft language on enzyme nomenclature. Just checking that you are interested in the agency's TA on the impact of this language and also draft language to add this to the other nomenclature systems. Please let me know if any additional questions. Best,
Sven

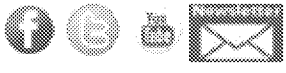
Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, November 06, 2015 11:37 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: enzyme name

"(iv) maintain the use of the Enzyme Nomenclature System, Recommendations of the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology on the Nomenclature and Classification of Enzymes by the Reactions they Catalyse, published in Enzyme Nomenclature 1992 (ISBN 0-12-227164-5), as supplemented.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



This language is provide by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, draft language and comments.

1. - *Can we soften the statutory text to say that EPA should maintain the nomenclature systems named unless EPA by rule and following some named criteria replaces the named system w something else?*

"(3) NOMENCLATURE.—

"(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

"(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

"(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and

"(iii) treat all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation—

"(I) cement, Portland, chemicals, CAS No. 65997–15–1;

"(II) cement, alumina, chemicals, CAS No. 65997–16–2;

"(III) glass, oxide, chemicals, CAS No. 65997–17–3;

"(IV) frits, chemicals, CAS No. 65997–18–4;

"(V) steel manufacture, chemicals, CAS No. 65997–19–5; and

"(VI) ceramic materials and wares, chemicals, CAS No. 66402–68–4.

"(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

"(i) IN GENERAL.—If an existing guidance allows for multiple nomenclature conventions, the Administrator shall—

"(I) maintain the nomenclature conventions for substances; and

"(II) develop new guidance that—

"(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and

"(bb) permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1).

"(ii) MULTIPLE CAS NUMBERS.—For any chemical substance appearing multiple times on the list under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.

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"(C) FLEXIBILITY.—Notwithstanding any requirement in paragraph (A) or (B) to maintain the use of particular nomenclature practices, the Administrator may modify such practices or establish alternative practices, subject to notice and comment, as warranted to achieve the purposes of this Act.

Commented [A1]: Further research reveals that the Soap and Detergent Nomenclature system was not established by rule, so it would be inconsistent to have the bill direct that it can only be modified by rule.

The system was established by order, as a way "to simplify reporting to EPA chemical substances identities." See 43 FR 16181 (1978). This was done to assist in the implementation of the original 8(a) reporting rule that established the TSCA Inventory, but it wasn't built into the rule itself, which was published in 42 FR 64572 (1977).

Commented [A2]: Achieve the purposes of this Act" was the basis for allowing Class 2 nomenclature in the first place. See TSCA 8(b)(2).

2. - *Can we figure out a section 5 process that may or may not be analogous to what the section 21 petition asked you to do that specifies a process by which someone can demonstrate that their chemical or feedstock is equivalent to something already on the inventory* for purposes of determining whether they need to submit a PMN ?Ideally ,such a process would not allow someone to ass*ert equivalence when none exists in a manner that erodes EPA's current authority to require PMNs when appropriate, but would provide a certain and specified process and timeframe for an applicant to be able to get the question answered.*

"SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.";

5(h) EXEMPTIONS.—

... [*Bill strikes 5(h)(2) from TSCA and renumbers 5(h)(1),(3-6) as 5(h)(1-5)*] ...

(6) PETITIONS FOR EXPANDED APPLICATION OF THE SOAP AND DETERGENT ASSOCIATION NOMENCLATURE SYSTEM.—

(A) IN GENERAL.—Any person may request that the Administrator change the terms of the Soap and Detergent Association Nomenclature System to allow the System to be used with an additional fat or oil that is equivalent to those identified by the Administrator in March 1978, in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances.'

(B) CRITERIA.—In reviewing any claim of equivalence in a petition under (A), the Administrator shall consider:

(i) Whether the additional fat or oil is characterized with sufficient specificity.

(ii) Whether the additional fat or oil is distinguishable, in any material respect, from the fats and oils that were already identified for use in 1978.

Commented [A3]: This sets the 1978 list as a fixed benchmark for evaluating similarity, which sets a clear baseline.

(iii) Whether derivatives of the additional fat or oil are or would be distinguishable,

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in any material respect, from the corresponding derivatives of the fats and oils that were already identified for use in 1978.

(C) CONTENT OF PETITION.—A petition under (A):

(i) must be submitted in the manner specified by the Administrator;

(ii) must claim that the additional fat or oil is equivalent to those identified by the Administrator in March 1978, in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances.'

(iii) must supply a rationale for the claim under (ii) that addresses each of the criteria under (B); and

(iv) must supply sufficient specific information, including all relevant citations and documents, to enable the Administrator to evaluate the validity of the claim and rationale under (ii) and (iii).

OPTION 1

(D) PROMPT REVIEW.—Within [XX] days of receiving a request under (A) and (B), the Administrator shall grant or deny the changes requested.

OPTION 2

(D) PROMPT REVIEW.—

(i) Within [XX] days of receiving a request under (A) and (B), the Administrator shall provide an opportunity for public notice and comment on the changes requested.

(ii) Within [XX] days of receiving a request under (A) and (B), the Administrator shall grant or deny the changes requested.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 11/19/2015 7:50:06 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA Request on enzyme name

Michal, thanks for the reminder. It's close and should be over to you today or tomorrow. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, November 19, 2015 2:39 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA Request on enzyme name

Any ETA on this?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Friday, November 6, 2015 2:19 PM
To: Freedhoff, Michal (Markey)
Subject: RE: Sen. Markey TSCA TA Request on enzyme name

Michal – thanks for clarifying. We'll be glad to provide a response. Please let me know if any additional questions. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, November 06, 2015 2:18 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA Request on enzyme name

Yes - interested in following:

- does epa currently utilize this Enzyme nomenclature system, in same way it uses the soap one, portland cement systems etc. Is it appropriate to add this one to the list, if one has such a list in statute in the first place?
- can we soften the statutory text to say that epa shd maintain the nomenclature systems named unless epa by rule and following some named criteria replaces the named system w something else?
- can we figure out a section 5 process that may or may not be analogous to what the section 21 petition asked you to do that specifies a process by which someone can demonstrate that their chemical or feedstock is equivalent to something already on the inventory for purposes of determining whether they need to submit a pmn? Ideally, such a process would not allow someone to assert equivalence when none exists in a manner that erodes epa's current authority to require pmns when appropriate, but would provide a certain and specified process and timeframe for an applicant to be able to get the question answered.

Thank you

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik
Sent: Friday, November 6, 2015 1:43 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on enzyme name

Michal,
Thank you for sending the draft language on enzyme nomenclature. Just checking that you are interested in the agency's TA on the impact of this language and also draft language to add this to the other nomenclature systems. Please let me know if any additional questions. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, November 06, 2015 11:37 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: enzyme name

> "(iv) maintain the use of the Enzyme Nomenclature System, Recommendations of the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology on the Nomenclature and Classification of Enzymes by the Reactions they Catalyse, published in Enzyme Nomenclature 1992 (ISBN 0-12-227164-5), as supplemented.

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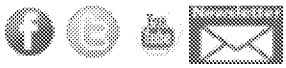

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 1/21/2016 12:15:08 AM
To: 'Espinosa, Sergio' [Sergio.Espinosa@mail.house.gov]
Subject: Administration Views on TSCA Reform Bills
Attachments: TSCA Reform Views.Pallone.pdf

Sergio,
Please see attached and let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 9/19/2016 2:41:34 PM
To: Couri, Jerry [JerryCouri@mail.house.gov]
Subject: HEC TSCA Section 5 Questions

Jerry,
Thanks for the request. I'm checking on the response. Please let me know if any additional questions. Thanks, Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Couri, Jerry [mailto:JerryCouri@mail.house.gov]
Sent: Monday, September 19, 2016 10:22 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Couple TSCA Section 5 Questions

Sven:

Happy Monday.

How many section 5(d)(3) lists have been issued since enactment? Where can I find them?

How many PMNs or SNUNs has been issued since date of enactment?

Thanks.

- Jerry

Gerald S. Couri
Senior Environmental Policy Advisor | Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Building | 202.226.9603 (direct)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 11/3/2015 7:27:39 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: TSCA Reform TA on Inhofe Substitute
Attachments: EPA TSCA Reform TA.Inhofe Substitute.docx

Michal,
This responds to Sen. Markey's request for technical assistance on the Inhofe substitute TSCA reform bill (EDW15923). The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Purpose: In the nature of a substitute.

S. 697

To amend the Toxic Substances Control Act to reauthorize and modernize that Act, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE INTENDED TO BE PROPOSED BY _____

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Frank R. Lautenberg Chemical Safety for the 21st Century Act".

SEC. 2. FINDINGS, POLICY, AND INTENT.

Section 2(c) of the Toxic Substances Control Act (15 U.S.C. 2601(c)) is amended—

(1) by striking "It is the intent" and inserting the following:

"(1) ADMINISTRATION.—It is the intent";

(2) in paragraph (1) (as so redesignated), by inserting ", as provided under this Act" before the period at the end; and

(3) by adding at the end the following:

"(2) REFORM.—This Act, including reforms in accordance with the amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act—

"(A) shall be administered in a manner that—

"(i) protects the health of children, pregnant women, the elderly, workers, consumers, the general public, and the environment from the risks of harmful exposures to chemical substances and mixtures; and

"(ii) ensures that appropriate information on chemical substances and mixtures is available to public health officials and first responders in the event of an

emergency; and

"(B) shall not displace or supplant common law rights of action or remedies for civil relief.".

SEC. 3. DEFINITIONS.

Section 3 of the Toxic Substances Control Act (15 U.S.C. 2602) is amended—

(1) by redesignating paragraphs (4), (5), (6), (7), (8), (9), (10), (11), (12), (13), and (14) as paragraphs (5), (6), (7), (8), (9), (10), (12), (13), (17), (18), and (19), respectively;

(2) by inserting after paragraph (3) the following:

"(4) CONDITIONS OF USE.—The term 'conditions of use' means the intended, known, or reasonably foreseeable circumstances the Administrator determines a chemical substance is manufactured, processed, distributed in commerce, used, or disposed of.";

(3) by inserting after paragraph (10) (as so redesignated) the following:

"(11) POTENTIALLY EXPOSED OR SUSCEPTIBLE POPULATION.—The term 'potentially exposed or susceptible population' means 1 or more groups—

"(A) of individuals within the general population who may be—

"(i) differentially exposed to chemical substances under the conditions of use; or

"(ii) susceptible to greater adverse health consequences from chemical exposures than the general population; and

"(B) that when identified by the Administrator may include such groups as infants, children, pregnant women, workers, and the elderly."; and

(4) by inserting after paragraph (13) (as so redesignated) the following:

"(14) SAFETY ASSESSMENT.—The term 'safety assessment' means an assessment of the risk posed by a chemical substance under the conditions of use, integrating hazard, use, and exposure information regarding the chemical substance.

"(15) SAFETY DETERMINATION.—The term 'safety determination' means a determination by the Administrator as to whether a chemical substance meets the safety standard under the conditions of use.

"(16) SAFETY STANDARD.—The term 'safety standard' means a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of injury to health or the environment will result from exposure to a chemical substance under the conditions of use, including no unreasonable risk of injury to—

"(A) the general population; or

"(B) any potentially exposed or susceptible population that the Administrator has identified as relevant to the safety assessment and safety determination for a chemical substance.".

SEC. 4. POLICIES, PROCEDURES, AND GUIDANCE.

The Toxic Substances Control Act is amended by inserting after section 3 (15 U.S.C. 2602) the following:

"SEC. 3A. POLICIES, PROCEDURES, AND GUIDANCE.

"(a) Definition of Guidance.—In this section, the term 'guidance' includes any significant written guidance of general applicability prepared by the Administrator.

"(b) Deadline.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop, after providing public notice and an opportunity for comment, any policies, procedures, and guidance the Administrator determines to be necessary to carry out sections 4, 4A, 5, and 6, including the policies, procedures, and guidance required by this section.

Commented [A1]: The combination of the fact that only "guidance" is limited to *significant* guidance, per 3A(a), and that "policies" and "procedures" are not so limited, may lead to the argument that EPA needs to take comment on even trivial policies and procedures per (b). This had been remedied in an earlier iteration, but for some reason that fix dropped.

"(c) Use of Science.—

"(1) IN GENERAL.—The Administrator shall establish policies, procedures, and guidance on the use of science in making decisions under sections 4, 4A, 5, and 6.

"(2) GOAL.—A goal of the policies, procedures, and guidance described in paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) REQUIREMENTS.—The policies, procedures, and guidance issued under this section shall ~~describe the manner in which the Administrator shall ensure that —~~ **ensure that—**

"(A) decisions made by the Administrator—

"(i) are based on information, procedures, measures, methods, and models employed in a manner consistent with the best available science;

"(ii) take into account the extent to which—

"(I) assumptions and methods are clearly and completely described and documented;

"(II) variability and uncertainty are evaluated and characterized; and

"(III) the information has been subject to independent verification and peer review; and

"(iii) are based on the weight of the scientific evidence, by which the Administrator considers all information in a systematic and integrative framework to consider the relevance of different information;

"(B) to the extent practicable and if appropriate, the use of peer review, standardized test design and methods, consistent data evaluation procedures, and good laboratory practices will be encouraged;

"(C) a clear description of each individual and entity that funded the generation or assessment of information, and the degree of control those individuals and entities had over the generation, assessment, and dissemination of information (including control over the design of the work and the publication of information) is made available; and

"(D) if appropriate, the recommendations in reports of the National Academy of Sciences that provide advice regarding assessing the hazards, exposures, and risks of chemical substances are considered.

"(d) Existing EPA Policies, Procedures, and Guidance.—The policies, procedures, and guidance described in subsection (b) shall incorporate~~, as appropriate, existing relevant hazard, exposure, and risk assessment guidelines and methodologies, data evaluation and quality criteria, testing methodologies, and other relevant guidelines and policies of the Environmental Protection Agency.~~ **existing relevant policies, procedures, and guidance, as appropriate and consistent with this Act.**

"(e) Review.—Not later than 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and not less frequently than once every 5 years thereafter, the Administrator shall—

"(1) review the adequacy of any policies, procedures, and guidance developed under this section, including animal, nonanimal, and epidemiological test methods and procedures for assessing and determining risk under this Act; and

"(2) after providing public notice and an opportunity for comment, revise the policies, procedures, and guidance if necessary to reflect new scientific developments or understandings.

"(f) Sources of Information.—In carrying out sections 4, 4A, 5, and 6, the Administrator shall take into consideration information relating to a chemical substance, including hazard and exposure information, under the conditions of use that is reasonably available to the Administrator, including information that is—

"(1) submitted to the Administrator pursuant to any rule, consent agreement, order, or other requirement of this Act, or on a voluntary basis, including pursuant to any request made under this Act, by—

"(A) manufacturers or processors of a substance;

"(B) the public;

"(C) other Federal departments or agencies; or

"(D) the Governor of a State or a State agency with responsibility for protecting health or the environment;

"(2) submitted to a governmental entity in any jurisdiction pursuant to a governmental requirement relating to the protection of health or the environment; or

"(3) identified through an active search by the Administrator of information sources that are publicly available or otherwise accessible by the Administrator.

"(g) Testing of Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator shall establish policies ~~and~~**,** procedures**, and guidance** for the testing of chemical substances or mixtures under section 4.

"(2) GOAL.—A goal of the policies ~~and~~**,** procedures**, and guidance** established under paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) CONTENTS.—The policies ~~and~~**,** procedures**, and guidance** established under paragraph (1) shall—

"(A) address how and when the exposure level or exposure potential of a chemical substance would factor into decisions to require new testing, subject to the condition

Commented [A2]: An earlier draft included the prescriptive 8(b) nomenclature provisions within this review authority, giving EPA authority to revise those provisions on review. That was dropped from this draft, so the nomenclature provisions are locked in.

that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential; **and**

"(B) describe the manner in which the Administrator will determine that additional information is necessary to carry out this Act, including information relating to potentially exposed or susceptible populations~~;~~.

~~"(C) require the Administrator to~~**"(4) EPIDEMIOLOGICAL STUDIES.—Before prescribing epidemiological studies of employees, the Administrator shall** consult with the Director of the National Institute for Occupational Safety and Health. ~~prior to prescribing epidemiologic studies of employees; and~~

~~"(D) require that prior to making a request or adopting a requirement for testing using vertebrate animals, the Administrator shall take into consideration, as appropriate and to the extent practicable, reasonably available—~~

~~"(i) toxicity information;~~

~~"(ii) computational toxicology and bioinformatics;~~

~~* 1 "(iii) high-throughput screening methods and the prediction models of those methods; and~~

~~* 2 "(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information.~~

"(h) Safety Assessments and Safety Determinations.—

"(1) SCHEDULE.—

"(A) IN GENERAL.—The Administrator shall inform the public regarding the schedule **and the resources necessary** for the completion of each safety assessment and safety determination as soon as practicable after designation as a high-priority substance pursuant to section 4A.

"(B) DIFFERING TIMES.—The Administrator may allot different times for different chemical substances in the schedules under this paragraph, subject to the condition that all schedules shall comply with the deadlines established under section 6.

"(C) ANNUAL ~~PLAN.—AT~~ PLAN.—

"(i) IN GENERAL.—At the beginning of each calendar year, the Administrator shall **publish an annual plan.**

"(ii) INCLUSIONS.—The annual plan shall—

"(I) identify the substances subject to safety assessments and safety determinations to be completed that year;

"(II) describe the status of each safety assessment and safety determination that has been initiated but not yet completed, including milestones achieved since the previous annual report; and

"(III) if the schedule for completion of a safety assessment and safety

determination prepared pursuant to subparagraph (A) has changed, include an updated schedule for that safety assessment and safety determination.

"(2) POLICIES AND PROCEDURES FOR SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.—

"(A) IN GENERAL.—The Administrator shall establish, by rule, policies and procedures regarding the manner in which the Administrator shall carry out section 6.

"(B) GOAL.—A goal of the policies and procedures under this paragraph shall be to make the basis of decisions of the Administrator clear to the public.

"(C) MINIMUM ~~REQUIREMENTS.—AT A MINIMUM, THE~~ REQUIREMENTS.—**The** policies and procedures under this paragraph ~~shall—~~ **shall, at a minimum—**

"(i) describe—

"(I) the manner in which the Administrator will identify informational needs and seek that information from the public;

"(II) the information (including draft safety assessments) that may be submitted by interested individuals or entities, including States; and

"(III) the criteria by which ~~that~~ information **submitted by interested individuals or entities** will be evaluated;

"(ii) require ~~the Administrator—~~ **that each draft and final safety assessment and safety determination of the Administrator include a description of—**

~~"(I)(aa) to define~~**"(I)(aa)** the scope of the safety assessment and safety determination to be conducted under section 6, including the hazards, exposures, **and** conditions of use **of the chemical substance**, and potentially exposed and susceptible populations that the Administrator ~~expects to consider in a safety assessment;~~ **has identified as relevant; and**

Commented [A3]: The assessment and determination will already have been conducted, at least in draft form, since this information is to be presented in the draft and final assessments themselves. This had been fixed in an earlier version.

~~"(bb) to explain~~**"(bb)** the basis for the scope of the safety assessment and safety determination;

~~and~~

~~"(cc) to accept comments regarding the scope of the safety assessment and safety determination; and~~

~~"(II)(aa) to identify the items described in subclause (I) that the Administrator has considered in the final safety assessment; and~~

~~"(bb) to explain the basis for the consideration of those items;~~

~~"(iii) describe~~**"(II)** the manner in which aggregate exposures, or significant subsets of exposures, to a chemical substance under the conditions of use ~~will be~~ **were** considered, and ~~explain~~ the basis for that consideration ~~in the final safety assessment;~~**;**

~~"(iv) require that each safety assessment and safety determination shall include—~~

~~"(I) a description of~~**"(III)** the weight of the scientific evidence of risk; and

~~"(II) a summary of~~**"(IV)** the information regarding the impact on health and the environment of the chemical substance that was used to make the assessment or determination, including, as available, mechanistic, animal toxicity, and epidemiology studies;

~~"(v)~~**"(iii)** establish a timely and transparent process for evaluating whether new information submitted or obtained after the date of a final safety assessment or safety determination warrants reconsideration of the safety assessment or safety determination; and

~~"(vi)~~**"(iv)** when relevant information is provided or otherwise made available to the Administrator, ~~shall~~ **require the Administrator to** consider the extent of Federal regulation under other Federal laws.

"(D) GUIDANCE.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop guidance to assist interested persons in developing their own draft safety assessments and other information for submission to the Administrator, which may be considered ~~at the discretion of~~ **by** the Administrator.

"(ii) REQUIREMENT.—The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing a draft safety assessment for consideration by the Administrator.

"(i) Publicly Available Information.—Subject to section 14, the Administrator shall—

"(1) make publicly available a nontechnical summary, and the final version, of each safety assessment and safety determination;

"(2) provide public notice and an opportunity for comment on each proposed safety assessment and safety determination; and

"(3) make public in a final safety assessment and safety determination—

"(A) the list of studies considered by the Administrator in carrying out the safety assessment or safety determination; and

"(B) the list of policies, procedures, and guidance that were followed in carrying out the safety assessment or safety determination.

"(j) Consultation With Science Advisory Committee on Chemicals.—

"(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish an advisory committee, to be known as the 'Science Advisory Committee on Chemicals' (referred to in this subsection as the 'Committee').

"(2) PURPOSE.—The purpose of the Committee shall be to provide independent advice and expert consultation, on the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title.

"(3) COMPOSITION.—The Committee shall be composed of representatives of such science, government, labor, public health, public interest, animal protection, industry, and

other groups as the Administrator determines to be advisable, including, at a minimum, representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible populations.

"(4) SCHEDULE.—The Administrator shall convene the Committee in accordance with such schedule as the Administrator determines to be appropriate, but not less frequently than once every 2 years.

"(5) RELATIONSHIP TO OTHER LAW.—All proceedings and meetings of the Committee shall be subject to the Federal Advisory Committee Act (5 U.S.C. App.).".

SEC. 5. TESTING OF CHEMICAL SUBSTANCES OR MIXTURES.

(a) In General.—Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amended—

(1) by striking subsections (a), (b), (c), (d), ~~and (g);~~**(e), and (g);**

~~(2) by redesignating subsections (e) and (f) as subsections (f) and (g), respectively;~~

~~(3) in subsection (f) (as so redesignated)—~~

~~(A) by striking "rule" each place it appears and inserting "rule, testing consent agreement, or order";~~

~~(B) by striking "under subsection (a)" each place it appears and inserting "under this subsection"; and~~

~~(C) in paragraph (1)—~~

~~(i) in subparagraph (A)(v), by inserting ", without taking into account cost or other nonrisk factors" after "the environment"; and~~

~~(ii) in subparagraph (B), in the last sentence, by striking "rulemaking";~~

~~(4) in subsection (g) (as so redesignated)—~~**(2) in subsection (f)—**

(A) in the first sentence—

(i) by striking "from cancer, gene mutations, or birth defects"; and

(ii) by inserting ", without taking into account cost or other nonrisk factors" before the period at the end; and

(B) by striking the last sentence; and

~~(5)~~**(3)** by inserting before subsection (f) ~~(as so redesignated)~~ the following:

"(a) Development of New Information on Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator may require the development of new information relating to a chemical substance or mixture in accordance with this section if the Administrator determines that the information is necessary—

"(A) to review a notice under section 5(d) or to perform a safety assessment or safety determination under section 6;

"(B) to implement a requirement imposed in a consent agreement or order issued under section 5(d)(4) or under a rule promulgated under section 6(d)(3);

"(C) pursuant to section 12(a)(4); or

"(D) at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority.

"(2) LIMITED TESTING FOR PRIORITIZATION PURPOSES.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the Administrator may require the development of new information for the purposes of section 4A.

"(B) PROHIBITION.—Testing required under subparagraph (A) shall not be required for the purpose of establishing or implementing a minimum information requirement.

"(C) LIMITATION.—The Administrator may require the development of new information pursuant to subparagraph (A) only if the Administrator determines that additional information is necessary to establish the priority of a chemical substance.

"(3) FORM.—The Administrator may require the development of information described in paragraph (1) or (2) by—

"(A) promulgating a rule;

"(B) entering into a testing consent agreement; or

"(C) issuing an order.

"(4) CONTENTS.—

"(A) IN GENERAL.—A rule, testing consent agreement, or order issued under this subsection shall include—

"(i) identification of the chemical substance or mixture for which testing is required;

"(ii) identification of the persons required to conduct the testing;

"(iii) test protocols and methodologies for the development of information for the chemical substance or mixture, including specific reference to any reliable nonanimal test procedures; and

"(iv) specification of the period within which individuals and entities required to conduct the testing shall submit to the Administrator the information developed in accordance with the procedures described in clause (iii).

"(B) CONSIDERATIONS.—In determining the procedures and period to be required under subparagraph (A), the Administrator shall take into consideration—

"(i) the relative costs of the various test protocols and methodologies that may be required; ~~and~~

"(ii) the reasonably foreseeable availability of facilities and personnel required to perform the testing**; and**

"(iii) the deadlines applicable to the Administrator under section 6(a).

"(5) CONSIDERATION OF FEDERAL AGENCY RECOMMENDATIONS.—The Administrator shall consider the recommendations of other Federal agencies regarding the chemical substances and mixtures to which the Administrator shall give priority consideration under this section.~~.~~

"(b) Statement of Need.—

"(1) IN GENERAL.—In promulgating a rule, entering into a testing consent agreement, or issuing an order for the development of additional information (including information on exposure or exposure potential) pursuant to this section, the Administrator shall—

"(A) identify the need intended to be met by the rule, agreement, or order;

"(B) explain why information reasonably available to the Administrator at that time is inadequate to meet that need, including a reference, as appropriate, to the information identified in paragraph (2)(B); and

"(C) explain the basis for any decision that requires the use of vertebrate animals.

"(2) EXPLANATION IN CASE OF ORDER.—

"(A) IN GENERAL.—If the Administrator issues an order under this section, the Administrator shall issue a statement providing a justification for why issuance of an order is warranted instead of promulgating a rule or entering into a testing consent agreement.

"(B) CONTENTS.—A statement described in subparagraph (A) shall contain a description of—

"(i) information that is readily accessible to the Administrator, including information submitted under any other provision of law;

"(ii) the extent to which the Administrator has obtained or attempted to obtain the information through voluntary submissions; and

"(iii) any information relied on in safety assessments for other chemical substances relevant to the chemical substances that would be the subject of the order.

"(c) Reduction of Testing on Vertebrates.—

"(1) IN GENERAL.—The Administrator shall minimize, to the extent practicable, the use of vertebrate animals in testing of chemical substances or mixtures, by—

"(A) ~~encouraging and facilitating—~~ **prior to making a request or adopting a requirement for testing using vertebrate animals, taking into consideration, as appropriate and to the extent practicable, reasonably available—**

"(i) toxicity information;

"(ii) computational toxicology and bioinformatics;

** **1** "(iii) high-throughput screening methods and the prediction models of

those methods; and

** **2** "(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information.~~;~~

"(B) encouraging and facilitating—

"(i) the use of integrated and tiered testing and assessment strategies;

"(ii) the use of best available science in existence on the date on which the test is conducted;

"(iii) the use of test methods that eliminate or reduce the use of animals while providing information of high scientific quality;

"(iv) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide reliable and useful information on other chemical substances in the category;

"(v) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests; and

"(vi) the submission of information from—

"(I) animal-based studies; and

"(II) emerging methods and models; and

~~"(B)~~**"(C)** funding research and validation studies to reduce, refine, and replace the use of animal tests in accordance with this subsection.

"(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new testing methods that are not based on vertebrate animals, the Administrator shall—

"(A) not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information under this title that can reduce, refine, or replace the use of vertebrate animals, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening;

"(B) as practicable, ensure that the strategic plan developed under subparagraph (A) is reflected in the development of requirements for testing under this section;

"(C) identify in the strategic plan developed under subparagraph (A) particular alternative test methods or testing strategies that do not require new vertebrate animal testing and are scientifically reliable, relevant, and capable of providing information of equivalent scientific reliability and quality to that which would be obtained from vertebrate animal testing;

"(D) provide an opportunity for public notice and comment on the contents of the plan developed under subparagraph (A), including the criteria for considering scientific reliability, relevance, and equivalent information and the test methods and strategies

identified in subparagraph (C);

"(E) beginning on the date that is 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing this subsection and goals for future alternative test methods implementation;

"(F) fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and testing strategies that reduce, refine, or replace the use of vertebrate animals in any testing under this title; and

"(G) identify synergies with the related information requirements of other jurisdictions to minimize the potential for additional or duplicative testing.

"(3) CRITERIA FOR ADAPTING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct testing of a chemical substance or mixture on vertebrate animals under this section, the Administrator may adapt or waive the requirement, if the Administrator determines that—

"(A) there is sufficient evidence from several independent sources of information to support a conclusion that a chemical substance or mixture has, or does not have, a particular property if the information from each individual source alone is insufficient to support the conclusion;

"(B) as a result of 1 or more physical or chemical properties of the chemical substance or mixture or other toxicokinetic considerations—

"(i) the substance cannot be absorbed; or

"(ii) testing for a specific endpoint is technically not practicable to conduct; or

"(C) a chemical substance or mixture cannot be tested in vertebrate animals at concentrations that do not result in significant pain or distress, because of physical or chemical properties of the chemical substance or mixture, such as a potential to cause severe corrosion or severe irritation to the tissues of the animal.

"(4) VOLUNTARY TESTING.—

"(A) IN GENERAL.—Any person developing information for submission under this title on a voluntary basis and not pursuant to any request or requirement by the Administrator shall first attempt to develop the information by means of an alternative or nonanimal test method or testing strategy that the Administrator has determined under paragraph (2)(C) to be scientifically reliable, relevant, and capable of providing equivalent information, before conducting new animal testing.

"(B) EFFECT OF PARAGRAPH.—Nothing in this paragraph—

"(i) requires the Administrator to review the basis on which the person is conducting testing described in subparagraph (A);

"(ii) prohibits the use of other test methods or testing strategies by any person for purposes other than developing information for submission under this title on a voluntary basis; or

"(iii) prohibits the use of other test methods or testing strategies by any person, subsequent to the attempt to develop information using the test methods and testing strategies identified by the Administrator under paragraph (2)(C).

"(d) Testing Requirements.—

"(1) IN GENERAL.—The Administrator may require the development of information by—

"(A) manufacturers and processors of the chemical substance or mixture; and

"(B) ~~subject to paragraph (3),~~ persons that begin to manufacture or process the chemical substance or **mixture** ~~mixture—~~

~~"(i)~~ after the effective date of the rule, testing consent agreement, or order.~~; but~~

~~"(ii) before the period ending on the later of—~~

~~"(I) 5 years after the date referred to in clause (i); or~~

~~* 3 "(II) the last day of the period that begins on the date referred to in clause (i) and that is equal to the period that the Administrator determines was necessary to develop the information.~~

"(2) DESIGNATION.—The Administrator may permit 2 or more persons identified in subparagraph (A) or (B) of paragraph (1) to designate 1 of the persons or a qualified third party—

"(A) to develop the information; and

"(B) to submit the information on behalf of the persons making the designation.

"(3) EXEMPTIONS.—

"(A) IN GENERAL.—A person otherwise subject to a rule, testing consent agreement, or order under this section may submit to the Administrator an application for an exemption on the basis that ~~the information~~ **submission of information by the applicant on the chemical substance or mixture would be duplicative of—**

"(i) information on the chemical substance or mixture that—

"(I) has been submitted to the Administrator pursuant to a rule, consent agreement, or order under this section; or

"(II) is being developed by a person designated under paragraph (2); or

"(ii) information on an equivalent chemical substance or mixture that—

"(I) has been submitted to the Administrator pursuant to a rule, consent agreement, or order under this section; or

"(II) is being developed by a person designated under paragraph (2).

"(B) FAIR AND EQUITABLE REIMBURSEMENT TO DESIGNEE.—

"(i) IN GENERAL.—If the Administrator accepts an application submitted under subparagraph (A), **before the end of the reimbursement period described in**

clause (iii), the Administrator shall direct the applicant to provide to the person designated under paragraph (2) fair and equitable reimbursement, as agreed to between the applicant and the designee.

"(ii) ARBITRATION.—If the applicant and a person designated under paragraph (2) cannot reach agreement on the amount of fair and equitable reimbursement, the amount shall be determined by arbitration.

"(iii) REIMBURSEMENT PERIOD.—For the purposes of this subparagraph, the reimbursement period for any information for a chemical substance or mixture is a period—

"(I) beginning on the date the information is submitted in accordance with a rule, testing consent agreement, or order under this section; and

"(II) ending on the later of—

"(aa) 5 years after the date referred to in subclause (I); or

** **3** ~~"(II)~~**"(bb)** the last day of the period that begins on the date referred to in ~~clause (i)~~ **subclause (I)** and that is equal to the period that the Administrator determines was necessary to develop the information.

"(C) TERMINATION.—If, after granting an exemption under this paragraph, the Administrator determines that no person designated under paragraph (2) has complied with the rule, testing consent agreement, or order, the Administrator shall—

"(i) by order, terminate the exemption; and

"(ii) notify in writing each person that received an exemption of the requirements with respect to which the exemption was granted.

"(4) TIERED TESTING.—

"(A) IN GENERAL.—Except as provided in subparagraph (D), the Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary.

"(B) SCREENING-LEVEL TESTS.—

"(i) IN GENERAL.—The screening-level tests required for a chemical substance or mixture may include tests for hazard (which may include in silico, in vitro, and in vivo tests), environmental and biological fate and transport, and measurements or modeling of exposure or exposure potential, as appropriate.

"(ii) USE.—Screening-level tests shall be used—

"(I) to screen chemical substances or mixtures for potential adverse effects; and

"(II) to inform a decision of the Administrator regarding whether more complex or targeted additional testing is necessary.

"(C) ADDITIONAL TESTING.—If the Administrator determines under subparagraph (B) that additional testing is necessary to provide more definitive information for

safety assessments or safety determinations, the Administrator may require more advanced tests for potential health or environmental effects or exposure potential.

"(D) ADVANCED TESTING WITHOUT SCREENING.—The Administrator may require more advanced testing without conducting screening-level testing when other information available to the Administrator justifies the advanced testing, pursuant to guidance developed by the Administrator under this section.

"(e) Transparency.—Subject to section 14, the Administrator shall make available to the public all testing consent agreements and orders and all information submitted under this section.".

(b) Conforming Amendment.—Section 104(i)(5)(A) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(5)(A)) is amended in the third sentence by ~~striking "section 4(e)" and inserting "section 4(f)".~~ **inserting "(as in effect on the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act)" after "Toxic Substances Control Act".**

SEC. 6. PRIORITIZATION SCREENING.

The Toxic Substances Control Act is amended by inserting after section 4 (15 U.S.C. 2603) the following:

"SEC. 4A. PRIORITIZATION SCREENING.

"(a) Prioritization Screening Process and List of Substances.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish, by rule, a risk-based screening process and ~~explicit~~ criteria for identifying existing chemical substances that are—

"(A) a high priority for a safety assessment and safety determination under section 6 (referred to in this Act as 'high-priority substances'); and

"(B) a low priority for a safety assessment and safety determination (referred to in this Act as 'low-priority substances').

"(2) INITIAL ~~LIST~~ **AND SUBSEQUENT LISTS** OF HIGH- AND LOW-PRIORITY SUBSTANCES.—

"(A) IN GENERAL.—Before the date of promulgation of the rule under paragraph (1) and not later than 180 days after the date of enactment of this section, the **Administrator shall** ~~Administrator—~~

~~"(i) shall take into consideration and~~ publish an initial list of high-priority substances and low-priority substances~~; and~~

~~"(ii) pursuant to section 6(b), may initiate or continue safety assessments and safety determinations for those high-priority substances~~.

"(B) REQUIREMENTS.—

"(i) IN GENERAL.—The initial list of chemical substances shall contain at least 10 high-priority substances, at least 5 of which are drawn from the list of chemical substances identified by the Administrator in the October 2014 TSCA Work Plan and subsequent updates, and at least 10 low-priority substances.

Commented [A4]: As we have commented before, the highlighted language should ideally be dropped, since there are other purposes for testing.

"(ii) SUBSEQUENTLY IDENTIFIED SUBSTANCES.—Insofar as possible, at least 50 percent of all substances subsequently identified by the Administrator as high-priority substances shall be drawn from the list of chemical substances identified by the Administrator in the October 2014 TSCA Work Plan and subsequent updates, until all Work Plan chemicals have been designated under this subsection.

"(iii) ~~PERSISTENCE AND BIOACCUMULATION.—IN~~ **PREFERENCES.—**

"(I) IN GENERAL.—In developing the initial list and in identifying additional high-priority substances, the Administrator shall give preference ~~to~~ **to—**

"(aa) chemical substances ~~scored as high for~~ **that, with respect to** persistence and bioaccumulation**, score high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012; and**

"(bb) chemical substances listed in the October 2014 TSCA Work Plan and subsequent updates **that are known human carcinogens and have high acute and chronic toxicity.**

"(II) METALS AND METAL COMPOUNDS.—In prioritizing and assessing metals and metal compounds, the Administrator shall use the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007 (or a successor document), and may use other applicable information consistent with the best available science.

"(C) ADDITIONAL CHEMICAL REVIEWS.—The Administrator shall, as soon as practicable and not later than—

"(i) 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 20 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 20 low-priority substances have been designated; and

"(ii) 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 25 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 25 low-priority substances have been designated.

"(3) IMPLEMENTATION.—

"(A) CONSIDERATION OF ACTIVE AND INACTIVE SUBSTANCES.—

"(i) ACTIVE SUBSTANCES.—In ~~carrying out~~ **implementing the prioritization screening process established under** paragraph (1), the Administrator shall take

into consideration active substances, as determined under section 8, which may include chemical substances on the interim list of active substances established under that section.

"(ii) INACTIVE SUBSTANCES.—In ~~carrying out~~ **implementing the prioritization screening process established under** paragraph (1), the Administrator may take into consideration inactive substances, as determined under section 8, that the Administrator determines—

"(I)(aa) have not been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) have the potential for high hazard and widespread exposure; or

"(II)(aa) have been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) with respect to which there exists the potential for residual high hazards or widespread exposures not otherwise addressed by the regulatory or other action.

"(iii) REPOPULATION.—

"(I) IN GENERAL.—On the completion of a safety determination under section 6 for a chemical substance, the Administrator shall remove the chemical substance from the list of high-priority substances established under this subsection.

"(II) ADDITIONS.—The Administrator shall add at least 1 chemical substance to the list of high-priority substances for each chemical substance removed from the list of high-priority substances established under this subsection, until a safety assessment and safety determination is completed for all **chemical substances not designated as high-priority.** ~~high-priority substances.~~

~~"(III) Low-priority substances.—If a low-priority substance is subsequently designated as a high-priority substance, the Administrator shall remove that substance from the list of low-priority substances.~~

"(B) TIMELY COMPLETION OF PRIORITIZATION SCREENING PROCESS.—

"(i) IN GENERAL.—The Administrator shall—

"(I) except as provided under paragraph (2), not later than 180 days after the effective date of the final rule under paragraph (1), begin the prioritization screening process; and

"(II) make every effort to complete the designation of all active substances as high-priority substances or low-priority substances in a timely manner.

"(ii) DECISIONS ON SUBSTANCES SUBJECT TO TESTING FOR PRIORITIZATION PURPOSES.—Not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, testing consent agreement, or order issued under section 4(a)(2), the Administrator shall designate the

chemical substance as a high-priority substance or low-priority substance.

"(iii) CONSIDERATION.—

"(I) IN GENERAL.—The Administrator shall screen substances and designate high-priority substances ~~taking into consideration~~ **consistent with** the ability of the Administrator to schedule and complete safety assessments and safety determinations under section 6 in ~~a timely manner.~~ **accordance with the deadlines under subsection (a) of that section.**

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of chemical substances to be subject to the prioritization screening process.

"(C) SCREENING OF CATEGORIES OF SUBSTANCES.—The Administrator may screen categories of chemical substances to ensure an efficient prioritization screening process to allow for timely and adequate designations of high-priority substances and low-priority substances and safety assessments and safety determinations for high-priority substances.

"(D) PUBLICATION OF LIST OF CHEMICAL SUBSTANCES.—The Administrator shall keep current and publish a list of chemical substances ~~that —~~ **that includes and identifies substances—**

~~"(i)~~ **"(i) that** are being considered in the prioritization screening process and the status of the ~~chemical~~ substances in the prioritization process~~, including those chemical substances~~**;**

"(ii) for which prioritization decisions have been ~~deferred; and~~ **postponed pursuant to subsection (b)(5), including the basis for the postponement; and**

~~"(ii)~~**"(iii) that** are designated as high-priority substances or low-priority substances, including the bases for such designations.

"(4) CRITERIA.—The criteria described in paragraph (1) shall account for—

"(A) the recommendation of the Governor of a State or a State agency with responsibility for protecting health or the environment from chemical substances appropriate for prioritization screening;

"(B) the hazard and exposure potential of the chemical substance (or category of substances), including persistence, bioaccumulation, and specific scientific classifications and designations by authoritative governmental entities;

"(C) the conditions of use or significant changes in the conditions of use of the chemical substance;

"(D) evidence and indicators of exposure potential to humans or the environment from the chemical substance, including potentially exposed or susceptible populations **and storage near significant sources of drinking water**;

"(E) the volume of a chemical substance manufactured or processed;

"(F) whether the volume of a chemical substance as reported ~~under~~ **pursuant to** a rule promulgated pursuant to section 8(a) has significantly increased or decreased

~~during the period beginning on the date of a previous report or the date on which a notice has been submitted under section 5(b) for that chemical substance~~;

"(G) the availability of information regarding potential hazards and exposures required for conducting a safety assessment or safety determination, with limited availability of relevant information to be a sufficient basis for designating a chemical substance as a high-priority substance, subject to the condition that limited availability shall not require designation as a high-priority substance; and

"(H) the extent of Federal or State regulation of the chemical substance or the extent of the impact of State regulation of the chemical substance on the United States, with existing Federal or State regulation of any uses evaluated in the prioritization screening process as a factor in designating a chemical substance to be a high-priority or a low-priority substance.

"(b) Prioritization Screening Process and Decisions.—

"(1) IN ~~GENERAL.—THE~~ GENERAL.—**In implementing the** prioritization screening process developed under subsection (a) ~~shall include a requirement that~~**,** the Administrator shall—

"(A) identify the chemical substances being considered for prioritization;

"(B) request interested persons to supply information regarding the chemical substances being considered;

"(C) apply the criteria identified in subsection (a)(4); and

"(D) subject to paragraph (5) and using the information available to the Administrator at the time of the decision, identify a chemical substance as a high-priority substance or a low-priority substance.

"(2) ~~INTEGRATION OF~~ **REASONABLY AVAILABLE** INFORMATION.—The prioritization screening decision regarding a chemical substance shall ~~integrate~~ **consider** any hazard and exposure information relating to the chemical substance that is **reasonably** available to the Administrator.

"(3) IDENTIFICATION OF HIGH-PRIORITY SUBSTANCES.—The Administrator—

"(A) shall identify as a high-priority substance a chemical substance that, relative to other active chemical substances, the Administrator determines has the potential for significant hazard and significant exposure;

"(B) may identify as a high-priority substance a chemical substance that, relative to other active chemical substances, the Administrator determines has the potential for significant hazard or significant exposure; and

"(C) may identify as a high-priority substance an inactive substance, as determined under subsection (a)(3)(A)(ii) and section 8(b), that the Administrator determines warrants a safety assessment and safety determination under section 6.

"(4) IDENTIFICATION OF LOW-PRIORITY SUBSTANCES.—The Administrator shall identify as a low-priority substance a chemical substance that the Administrator concludes has information sufficient to establish that the chemical substance is likely to meet the safety

standard.

"(5) ~~DEFERRING~~ **POSTPONING** A DECISION.—If the Administrator determines that additional information is ~~required~~ **needed** to establish the priority of a chemical substance under this section, the Administrator may ~~defer the~~ **postpone a** prioritization screening decision for a reasonable period—

"(A) to allow for the submission of additional information by an interested person and for the Administrator to evaluate the additional information; or

"(B) to require the development of information pursuant to a rule, testing consent agreement, or order issued under section 4(a)(2).

"(6) DEADLINES FOR SUBMISSION OF INFORMATION.—If the Administrator requests the development or submission of information under this section, the Administrator shall establish a deadline for submission of the information.

"(7) NOTICE AND COMMENT.—The Administrator shall—

"(A) publish, including in the Federal Register, the proposed decisions made under paragraphs (3), (4), and (5) and the basis for the decisions;

~~and~~**"(B) identify the information and analysis on which the decisions are based; and**

~~"(B)~~ **"(C)** provide 90 days for public comment.

"(8) REVISIONS OF PRIOR DESIGNATIONS.—

"(A) IN GENERAL.—At any time, ~~and at the discretion of the Administrator,~~ the Administrator may revise the designation of a chemical substance as a high-priority substance or a low-priority substance based on information available to the Administrator after the date of the determination under paragraph (3) or (4).

"(B) LIMITED AVAILABILITY.—If limited availability of relevant information was a basis in the designation of a chemical substance as a high-priority substance, the Administrator shall reevaluate the prioritization screening of the chemical substance on receiving the relevant information.

"(9) OTHER INFORMATION RELEVANT TO PRIORITIZATION.—

"(A) IN GENERAL.—If, after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a State proposes an administrative action or enacts a statute or takes an administrative action to prohibit or otherwise restrict the manufacturing, processing, distribution in commerce, or use of a chemical substance that the Administrator has not designated as a high-priority substance, the Governor or State agency with responsibility for implementing the statute or administrative action shall notify the Administrator.

"(B) REQUESTS FOR INFORMATION.—Following receipt of a notification provided under subparagraph (A), the Administrator may request any available information from the Governor or the State agency with respect to—

"(i) scientific evidence related to the hazards, exposures and risks of the chemical substance under the conditions of use which the statute or administrative

action is intended to address;

"(ii) any State or local conditions which warranted the statute or administrative action;

"(iii) the statutory or administrative authority on which the action is based; and

"(iv) any other available information relevant to the prohibition or other restriction, including information on any alternatives considered and their hazards, exposures, and risks.

"(C) PRIORITIZATION SCREENING.—The Administrator shall conduct a prioritization screening under this subsection for all substances that—

"(i) are the subject of notifications received under subparagraph (A); and

"(ii) the Administrator determines—

"(I) are likely to have significant health or environmental impacts;

"(II) are likely to have significant impact on interstate commerce; or

"(III) have been subject to a prohibition or other restriction under a statute or administrative action in 2 or more States.

"(D) **POST-PRIORITIZATION NOTICE.—If, after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a State proposes or takes an administrative action or enacts a statute to prohibit or otherwise restrict the manufacturing, processing, distribution in commerce, or use of a high-priority substance, after the date on which the deadline established pursuant to subsection (a) of section 6 for completion of the safety determination under that subsection expires but before the date on which the Administrator publishes the safety determination under that subsection, the Governor or State agency with responsibility for implementing the statute or administrative action shall—**

"(i) notify the Administrator; and

"(ii) provide the scientific and legal basis for the action.

"(E) AVAILABILITY TO PUBLIC.—Subject to section 14 and any applicable State law regarding the protection of confidential information provided to the State or to the Administrator, the Administrator shall make information received from a Governor or State agency under subparagraph (A) publicly available.

"~~(E)~~**"(F)** EFFECT OF PARAGRAPH.—Nothing in this paragraph shall preempt a State statute or administrative action, require approval of a State statute or administrative action, or apply section 15 to a State.

"(10) REVIEW.—Not less frequently than once every 5 years after the date on which the process under this subsection is established, the Administrator shall—

"(A) review the process on the basis of experience and taking into consideration resources available to efficiently and effectively screen and prioritize chemical substances; and

"(B) if necessary, modify the prioritization screening process.

"(11) EFFECT.—Subject to section 18, a designation by the Administrator under this section with respect to a chemical substance shall not affect—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance; or

"(B) the regulation of those activities.

"(c) Additional Priorities for Safety Assessments and Determinations.—

"(1) REQUIREMENTS.—

"(A) IN GENERAL.—The ~~prioritization screening process developed~~ **rule promulgated** under subsection (a) shall—

"(i) include a process by which a manufacturer or processor of an active chemical substance that has not been designated a high-priority substance or is not in the process of a prioritization screening by the Administrator, may request that the Administrator designate the substance as an additional priority for a safety assessment and safety determination, subject to the payment of fees pursuant to section ~~26(b)(3)(E)~~ **26(b)(3)(D)**;

Commented [A5]: Should probably be "and".

"(ii) specify the information to be provided in such requests; and

"(iii) specify the criteria **(which may include criteria identified in subsection (a)(4)) that** the Administrator shall use to determine whether or not to grant such a request, which shall include whether the substance is subject to restrictions imposed by statutes enacted or administrative actions taken by 1 or more States on the manufacture, processing, distribution in commerce, or use of the substance.

"(B) PREFERENCE.—Subject to paragraph (2), in deciding whether to grant requests under this subsection the Administrator shall give a preference to requests concerning substances for which the Administrator determines that restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.

"(C) EXCEPTIONS.—Chemical substances for which requests have been granted under this subsection shall not be subject to subsection (a)(3)(A)(iii) or section 18(b).

"(2) LIMITATIONS.—In considering whether to grant a request submitted under paragraph (1), the Administrator shall ensure that—

"(A) ~~if a sufficient number of additional priority requests meet the requirements of paragraph (1),~~ **the number of substances designated to undergo safety assessments and safety determinations under the process and criteria pursuant to paragraph (1) is** not less than 25 percent, or more than 30 percent, of the cumulative number of substances designated to undergo safety assessments and safety determinations under subsections (a)(2) and (b)(3) ~~are substances designated under the process and criteria pursuant to paragraph (1);~~**(except that if less than 25 percent are received by the Administrator, the Administrator shall grant each request that meets the requirements of paragraph (1));**

"(B) the resources allocated to conducting safety assessments and safety determinations for additional priorities designated under this subsection are

proportionate to the number of such substances relative to the total number of substances **currently** designated to undergo safety assessments and safety determinations under this section; and

"(C) the number of additional priority requests stipulated under subparagraph (A) is in addition to the total number of high-priority substances identified under subsections (a)(2) and (b)(3).

"(3) ADDITIONAL REVIEW OF WORK PLAN CHEMICALS FOR SAFETY ASSESSMENT AND SAFETY DETERMINATION.—In the case of a request under paragraph (1) with respect to a chemical substance identified by the Administrator in the October 2014 **TSCA** Work Plan—

"(A) the 30-percent cap specified in paragraph (2)(A) shall not apply and the addition of Work Plan chemicals shall be at the discretion of the Administrator; and

"(B) notwithstanding paragraph (1)(C), requests for additional Work Plan chemicals under this subsection shall be considered high-priority chemicals subject to section 18(b) but not subsection (a)(3)(A)(iii).

"(4) REQUIREMENTS.—

"(A) IN GENERAL.—The public shall be provided notice and an opportunity to comment on requests submitted under this subsection.

"(B) DECISION BY ADMINISTRATOR.—Not later than 180 days after the date on which the Administrator receives a request under this subsection, the Administrator shall decide whether or not to grant the request.

"(C) ASSESSMENT AND DETERMINATION.—If the Administrator grants a request under this subsection, the safety assessment and safety determination—

"(i) shall be conducted in accordance with the deadlines and other requirements of sections 3A(i) and 6; and

"(ii) shall not be expedited or otherwise subject to special treatment relative to high-priority substances designated pursuant to subsection (b)(3) that are undergoing safety assessments and safety determinations.".

SEC. 7. NEW CHEMICALS AND SIGNIFICANT NEW USES.

Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.";

(2) by striking subsection (b);

(3) by redesignating subsection (a) as subsection (b);

(4) by redesignating subsection (i) as subsection (a) and moving the subsection so as to

appear at the beginning of the section;

(5) in subsection (b) (as so redesignated)—

(A) in the subsection heading, by striking "In General" and inserting "Notices";

(B) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking "subsection (h)" and inserting "paragraph (3) and subsection (h)"; and

(ii) in the matter following subparagraph (B)—

(I) by striking "subsection (d)" and inserting "subsection (c)"; and

(II) by striking "and such person complies with any applicable requirement of subsection (b)"; and

(C) by adding at the end the following:

"(3) ARTICLE CONSIDERATION.—The Administrator may require ~~the~~ notification **under this section** for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(B) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule warrants notification.";

(6) by redesignating subsections (c) and (d) as subsections (d) and (c), respectively, and moving subsection (c) (as so redesigned) so as appear after subsection (b) (as redesignated by paragraph (3));

(7) in subsection (c) (as so redesignated)—

(A) by striking paragraph (1) and inserting the following:

"(1) IN GENERAL.—The notice required by subsection (b) shall include, with respect to a chemical substance—

"(A) the information required by sections 720.45 and 720.50 of title 40, Code of Federal Regulations (or successor regulations); and

"(B) **all known or reasonably ascertainable** information regarding conditions of use and reasonably anticipated exposures.";

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A)—

(I) by striking "subsection (a)" and inserting "subsection (b)"; and

(II) by striking "or of data under subsection (b)";

(ii) in subparagraph (A), by adding "and" after the semicolon at the end;

(iii) in subparagraph (B), by striking "; and" and inserting a period; and

(iv) by striking subparagraph (C); and

(C) in paragraph (3), by striking "subsection (a) and for which the notification

period prescribed by subsection (a), (b), or (c)" and inserting "subsection (b) and for which the notification period prescribed by subsection (b) or (d)";

(8) by striking subsection (d) (as redesignated by paragraph (6)) and inserting the following:

"(d) Review of Notice.—

"(1) INITIAL REVIEW.—

"(A) IN GENERAL.—Subject to subparagraph (B), not later than 90 days after the date of receipt of a notice submitted under subsection (b), the Administrator shall—

"(i) conduct an initial review of the notice;

"(ii) as needed, develop a profile of the relevant chemical substance and the potential for exposure to humans and the environment; and

"(iii) make ~~any necessary~~ **a** determination under paragraph (3).

"(B) EXTENSION.—Except as provided in paragraph (5), the Administrator may extend the period described in subparagraph (A) for good cause for 1 or more periods, the total of which shall be not more than 90 days.

"(2) INFORMATION SOURCES.—In evaluating a notice under paragraph (1), the Administrator shall take into consideration—

"(A) any relevant information identified in subsection (c)(1); and

"(B) any other relevant additional information available to the Administrator.

"(3) DETERMINATIONS.—Before the end of the applicable period for review under paragraph (1), based on the information described in paragraph (2), and subject to section 18(g), the Administrator shall determine that—

Commented [A6]: As we have previously commented, it makes no sense to say that EPA determinations are subject to the general savings provision in the preemption section.

"(A) the relevant chemical substance or significant new use is not likely to meet the safety standard, in which case the Administrator shall take appropriate action under paragraph (4);

"(B) the relevant chemical substance or significant new use is likely to meet the safety standard, in which case the Administrator shall allow the review period to expire without additional restrictions; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraphs (4) and (5).

"(4) RESTRICTIONS.—

"(A) DETERMINATION BY ADMINISTRATOR.—

"(i) IN GENERAL.—If the Administrator makes a determination under subparagraph (A) or (C) of paragraph (3) with respect to a notice submitted under subsection (b)—

"(I) the Administrator, before the end of the applicable period for review under paragraph (1) and by consent agreement or order, as appropriate, shall

prohibit or otherwise restrict the manufacture, processing, use, distribution in commerce, or disposal (as applicable) of the chemical substance, or of the chemical substance for a significant new use, without compliance with the restrictions specified in the consent agreement or order that the Administrator determines are sufficient to ensure that the chemical substance or significant new use is likely to meet the safety standard; and

"(II) no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, except in compliance with the restrictions specified in the consent agreement or order.

"(ii) LIKELY TO MEET STANDARD.—If the Administrator makes a determination under subparagraph (B) of paragraph (3) with respect to a chemical substance or significant new use for which a notice was submitted under subsection (b), ~~at the end~~ **then notwithstanding any remaining portion** of the applicable period for review under paragraph (1), the submitter of the notice may commence manufacture for commercial purposes of the chemical substance or manufacture or processing of the chemical substance for a significant new use.

"(B) REQUIREMENTS.—Not later than 90 days after issuing a consent agreement or order under subparagraph (A), the Administrator shall—

"(i) ~~take into consideration~~ **consider** whether to promulgate a rule pursuant to subsection (b)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance~~, or of the chemical substance for a new use, that is not in compliance with~~ **that does not conform to** the restrictions imposed by the consent agreement or order; and

"(ii)(I) initiate a rulemaking described in clause (i); or

"(II) publish a statement describing the reasons of the Administrator for not initiating a rulemaking.

"(C) INCLUSIONS.—A prohibition or other restriction under subparagraph (A) may include, as appropriate—

"(i) subject to section 18(g), a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the minimum warnings and instructions to be prescribed by the Administrator

Commented [A7]: As we have previously commented, it makes no sense to say that EPA's imposition of a labeling requirement is subject to the general savings provision in the preemption section, and it's confusing that EPA's imposition of other requirements is not so subject.

"(ii) a requirement that manufacturers or processors of the chemical substance shall—

"(I) make and retain records of the processes used to manufacture or process, as applicable, the chemical substance; or

"(II) monitor or conduct such additional tests as are reasonably necessary to address potential risks from the manufacture, processing, distribution in commerce, use, or disposal, as applicable, of the chemical substance, subject

to section 4;

"(iii) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce—

"(I) in general; or

"(II) for a particular use;

"(iv) a prohibition or other restriction of—

"(I) the manufacture, processing, or distribution in commerce of the chemical substance for a significant new use;

"(II) any method of commercial use of the chemical substance; or

"(III) any method of disposal of the chemical substance; or

"(v) a prohibition or other restriction on the manufacture, processing, or distribution in commerce of the chemical substance—

"(I) in general; or

"(II) for a particular use.

"(D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines ~~ranks high for~~**, with respect to** persistence and bioaccumulation, **scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012,** the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient to ensure that the chemical substance is likely to meet the safety standard, reduce potential exposure to the substance to the maximum extent practicable.

"(E) WORKPLACE ~~EXPOSURES.—THE~~ EXPOSURES.—**To the extent practicable, the** Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.

"(F) DEFINITION OF REQUIREMENT.—For purposes of this Act, the term 'requirement' as used in this section does not displace common law.

Commented [A8]: As we have commented previously, it makes no sense to say the term "requirement" does not displace comment law (and even if that made sense conceptually, section 6 mostly uses the word "restrictions", not "requirements"). This provision, along with the references to section 18(g), seem like an awkward ways to reinforce non-preemption of common law.

"(5) ADDITIONAL INFORMATION.—If the Administrator determines under paragraph (3)(C) that additional information is necessary to conduct a review under this subsection, the Administrator—

"(A) shall provide an opportunity for the submitter of the notice to submit the additional information;

"(B) may, by agreement with the submitter, extend the review period for a reasonable time to allow the development and submission of the additional information;

"(C) may promulgate a rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information; and

"(D) on receipt of information the Administrator finds supports the determination

under paragraph (3), shall promptly make the determination.";

(9) by striking subsections (e) through (g) and inserting the following:

"(e) Notice of Commencement.—

"(1) IN GENERAL.—Not later than 30 days after the date on which a manufacturer that has submitted a notice under subsection (b) commences nonexempt commercial manufacture of a chemical substance, the manufacturer shall submit to the Administrator a notice of commencement that identifies—

"(A) the name of the manufacturer; and

"(B) the initial date of nonexempt commercial manufacture.

"(2) WITHDRAWAL.—A manufacturer or processor that has submitted a notice under subsection (b), but that has not commenced nonexempt commercial manufacture or processing of the chemical substance, may withdraw the notice.

"(f) Further Evaluation.—The Administrator may review a chemical substance under section 4A at any time after the Administrator receives—

"(1) a notice of commencement for a chemical substance under subsection (e); or

"(2) new information regarding the chemical substance.

"(g) Transparency.—Subject to section 14, the Administrator shall make available to the public—

"(1) all notices, determinations, consent agreements, rules, and orders ~~of~~ **submitted under this section or made by** the Administrator **under this section**; and

"(2) all information submitted or issued under this section."; and

(10) in subsection (h)—

(A) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking "(a) or"; and

(ii) in subparagraph (A), by inserting ", without taking into account cost or other nonrisk factors" after "the environment";

(B) by striking paragraph (2);

(C) by redesignating paragraphs (3) through (6) as paragraphs (2) through (5), respectively;

(D) in paragraph (2) (as so redesignated), in the matter preceding subparagraph (A), by striking "subsections (a) and (b)" and inserting "subsection (b)";

(E) in paragraph (3) (as so redesignated)—

(i) in the first sentence, by striking "will not present an unreasonable risk of injury to health or the environment" and inserting "will meet the safety standard"; and

(ii) by striking the second sentence;

(F) in paragraph (4) (as so redesignated), by striking "subsections (a) and (b)" and inserting "subsection (b)"; and

(G) in paragraph (5) (as so redesignated), in the first sentence, by striking "paragraph (1) or (5)" and inserting "paragraph (1) or (4)".

SEC. 8. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.

Section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.";

(2) by redesignating subsections (e) and (f) as subsections ~~(g)~~**(h)** and ~~(h)~~**(i)**, respectively;

(3) by striking subsections (a) through (d) and inserting the following:

"(a) In General.—The Administrator—

"(1) shall conduct a safety assessment and make a safety determination of each high-priority substance in accordance with subsections (b) and (c);

"(2) shall, as soon as practicable and not later than 6 months after the date on which a chemical substance is designated as a high-priority substance, define and publish the scope of the safety assessment and safety determination to be conducted pursuant to this section, including the hazards, exposures, conditions of use, and potentially exposed or susceptible populations that the Administrator expects to consider;

"(3) as appropriate based on the results of a safety determination, shall establish restrictions pursuant to subsection (d);

"(4) shall complete **and publish** a safety assessment and safety determination not later than 3 years after the date on which a chemical substance is designated as a high-priority substance;

"(5) shall promulgate ~~a~~ **any necessary** final rule pursuant to subsection (d) by not later than 2 years after the date on which the safety determination is completed; ~~and~~

"(6) may extend any deadline under paragraph (4) ~~or (5) for a reasonable period of time after an adequate public justification~~ **for not more than 1 year, if information relating to the high-priority substance, required to be developed in a rule, order, or consent agreement under section 4—**

"(A) has not yet been submitted to the Administrator; or

"(B) was submitted to the Administrator—

"(i) within the time specified in the rule, order, or consent agreement pursuant to section 4(a)(4)(A)(iv); and

"(ii) on or after the date that is 120 days before the expiration of the deadline described in paragraph (4); and

"(7) may extend the deadline under paragraph (5) for not more than 2 years, subject to the condition that the aggregate length of all extensions of deadlines under this subsection~~, plus any deferral under subsection (c)(2),~~ does not exceed 2 years.

"(b) Prior Actions and Notice of Existing Information.—

"(1) PRIOR-INITIATED ASSESSMENTS.—

"(A) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a safety assessment or safety determination regarding a chemical substance, or from continuing or completing such a safety assessment or safety determination ~~that was initiated before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act~~, prior to the effective date of the policies ~~and~~**,** procedures**, and guidance** required to be established by the Administrator under section 3A or 4A.

"(B) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—As policies and procedures under section 3A and 4A are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing safety assessments and safety determinations.

"(2) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—Nothing in this Act requires the Administrator to revise or withdraw a completed safety assessment, safety determination, or rule solely because the action was completed prior to the completion of a policy or procedure established under section 3A or 4A, and the validity of a completed assessment, determination, or rule shall not be determined based on the content of such a policy or procedure.

"(3) NOTICE OF EXISTING INFORMATION.—

"(A) IN GENERAL.—The Administrator shall, where such information is available, take notice of existing information regarding hazard and exposure published by other Federal agencies and the National Academies and incorporate the information in safety assessments and safety determinations with the objective of increasing the efficiency of the safety assessments and safety determinations.

"(B) INCLUSION OF INFORMATION.—Existing information described in subparagraph (A) should be included to the extent practicable and where the Administrator determines the information is relevant and scientifically reliable.

"(c) Safety Determinations.—

"(1) IN GENERAL.—Based on a review of the information available to the Administrator, including draft safety assessments submitted by interested persons **pursuant to section 3A(h)(2)(D)**, and subject to section 18**(g)**, the Administrator shall ~~determine that—~~ **determine—**

~~"(A)~~ **"(A) by order, that** the relevant chemical substance meets the safety standard;

"(B) **that** the relevant chemical substance does not meet the safety standard, in which case the Administrator shall, by rule under subsection (d)—

"(i) impose restrictions necessary to ensure that the chemical substance meets the safety standard under the conditions of use; or

Commented [A9]: As we have previously commented, it makes no sense to say that EPA determinations are subject to the general savings provision in the preemption section.

"(ii) if the safety standard cannot be met with the application of **other** restrictions **under subsection (d)(3)**, ban or phase out the chemical substance, as appropriate; or

"(C) **that** additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (2).

"(2) ADDITIONAL INFORMATION.—If the Administrator determines that additional information is necessary to make a safety assessment or safety determination for a high-priority substance, the Administrator—

"(A) shall provide an opportunity for interested persons to submit the additional information;

"(B) may promulgate a rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information;

"(C) may defer, for a reasonable period consistent with the deadlines described in subsection (a), a safety assessment and safety determination until after receipt of the information; and

"(D) consistent with the deadlines described in subsection (a), on receipt of information the Administrator finds supports the safety assessment and safety determination, shall make a determination under paragraph (1).

"(3) ESTABLISHMENT OF DEADLINE.—In requesting the development or submission of information under this section, the Administrator shall establish a deadline for the submission of the information.

"(d) Rule.—

"(1) IMPLEMENTATION.—If the Administrator makes a determination under subsection (c)(1)(B) with respect to a chemical substance, the Administrator shall promulgate a rule establishing restrictions necessary to ensure that the chemical substance meets the safety standard.

"(2) SCOPE.—

"(A) IN GENERAL.—The rule promulgated pursuant to this subsection—

"(i) may apply to mixtures containing the chemical substance, as appropriate;

"(ii) shall include dates by which compliance is mandatory, which—

"(I) shall be as soon as practicable**, but not later than 4 years after the date of promulgation of the rule, except in the case of a use exempted under paragraph (5)**;

"(II) in the case of a ban or phase-out of the chemical substance, shall implement the ban or phase-out in as short a period as practicable; ~~and~~

"(III) as determined by the Administrator, may vary for different affected persons; and

"(IV) following a determination by the Administrator that compliance is technologically or economically infeasible within the timeframe specified in subclause (I), shall provide up to an additional 18 months for compliance to be mandatory;

"(iii) shall exempt replacement parts that are manufactured prior to the effective date of the rule for articles that are first manufactured prior to the effective date of the rule unless the Administrator finds the replacement parts contribute significantly to the identified risk; ~~and~~

"(iv) shall, in selecting among prohibitions and other restrictions, apply such prohibitions or other restrictions to **an article or category of** articles containing the chemical substance only to the extent necessary to address the identified risks **from exposure to the chemical substance from the article or category of articles,** in order to determine that the chemical substance meets the safety standard**; and**

"(v) shall, when the Administrator determines that the chemical substance does not meet the safety standard for a potentially exposed or susceptible population, apply prohibitions or other restrictions necessary to ensure that the substance meets the safety standard for that population.

"(B) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines ~~ranks high for~~**, with respect to** persistence and bioaccumulation, **scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012,** the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient to ensure that the chemical substance meets the safety standard, reduce exposure to the substance to the maximum extent practicable.

"(C) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health before adopting any prohibition or other restriction under this subsection to address workplace exposures.

"(D) DEFINITION OF REQUIREMENT.—For the purposes of this Act, the term 'requirement' as used in this section does not displace common law.

"(3) ~~RESTRICTIONS.—A~~ **RESTRICTIONS.—Subject to section 18, a** restriction under paragraph (1) may include, as appropriate—

"(A) ~~subject to section 18,~~ a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the minimum warnings and instructions to be prescribed by the Administrator;

"(B) a requirement that manufacturers or processors of the chemical substance shall—

"(i) make and retain records of the processes used to manufacture or process

Commented [A10]: Consistent with earlier comments, this makes no sense, and in addition this refers only to section 18, not to section 18(g) like the preceding references. This is an inconsistency that was fixed in an earlier draft. At least in this draft this reference is moved to the chapeau, so it affects all restrictions, not just labeling, but a corresponding change was not made with respect to section 5 restrictions.

the chemical substance;

"(ii) describe and apply the relevant quality control procedures followed in the manufacturing or processing of the substance; or

"(iii) monitor or conduct tests that are reasonably necessary to ensure compliance with the requirements of any rule under this subsection;

"(C) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce;

"(D) a requirement to ban or phase out, or ~~any other rule regarding,~~ **otherwise restrict** the manufacture, processing, or distribution in commerce of the chemical substance for—

"(i) a particular use;

"(ii) a particular use at a concentration in excess of a level specified by the Administrator; or

"(iii) all uses;

"(E) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce for—

"(i) a particular use; or

"(ii) a particular use at a concentration in excess of a level specified by the Administrator;

"(F) a requirement to ban, phase out, or otherwise restrict any method of commercial use of the chemical substance;

"(G) a requirement to ban, phase out, or otherwise restrict any method of disposal of the chemical substance or any article containing the chemical substance; and

"(H) a requirement directing manufacturers or processors of the chemical substance to give notice of the Administrator's determination under subsection (c)(1)(B) to distributors in commerce of the chemical substance and, to the extent reasonably ascertainable, to other persons in the chain of commerce in possession of the chemical substance.

"(4) ANALYSIS FOR RULEMAKING.—

"(A) CONSIDERATIONS.—In deciding which restrictions to impose under paragraph (3) as part of developing a rule under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

"(B) ALTERNATIVES.—As part of the analysis, the Administrator shall review any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking.

"(C) PUBLIC AVAILABILITY.—In proposing a rule under paragraph (1), the

Administrator shall make publicly available any analysis conducted under this paragraph.

"(D) STATEMENT REQUIRED.—In making final a rule under paragraph (1), the Administrator shall include a statement describing how the analysis considered under subparagraph (A) was taken into account.

"(5) EXEMPTIONS.—

"(A) IN GENERAL.—The Administrator may ~~exempt 1 or more uses of a chemical substance from any restriction in~~, **as part of** a rule promulgated under paragraph (1) **or in a separate rule, exempt 1 or more uses of a chemical substance from any restriction in a rule promulgated under paragraph (1)** if the Administrator determines that—

"(i) the ~~rule~~ **restriction** cannot be complied with, without—

"(I) harming national security;

"(II) causing significant disruption in the national economy due to the lack of availability of a chemical substance; or

"(III) interfering with a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; or

"(ii) the use of the chemical substance, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

"(B) EXEMPTION ANALYSIS.—In proposing a rule under ~~paragraph (1) that includes an exemption under~~ this paragraph, the Administrator shall make publicly available any analysis conducted under this paragraph to assess the need for the exemption.

"(C) STATEMENT REQUIRED.—In making final a rule under ~~paragraph (1) that includes an exemption under~~ this paragraph, the Administrator shall include a statement describing how the analysis considered under subparagraph (B) was taken into account.

"(D) ANALYSIS IN CASE OF BAN OR PHASE-OUT.—In determining whether an exemption should be granted under this paragraph for a chemical substance for which a ban or phase-out is **included in a** proposed **or final rule under paragraph (1)**, the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the 1 or more ~~technically and economically feasible~~ alternatives to the chemical substance **the Administrator determines to be technically and economically feasible and** most likely to be used in place of the chemical substance under the conditions of use ~~if the rule is promulgated~~.

"(E) CONDITIONS.—As part of a rule promulgated under **this** paragraph~~(1)~~, the Administrator shall include conditions ~~in any exemption established under this paragraph~~, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent that the Administrator determines the conditions are

necessary to protect health and the environment while achieving the purposes of the exemption.

"(F) DURATION.—

"(i) IN GENERAL.—The Administrator shall establish, as part of a rule under ~~paragraph (1) that contains an exemption under~~ this paragraph, a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis.

"(ii) AUTHORITY OF ADMINISTRATOR.—The Administrator, by rule, may extend, modify, or eliminate ~~the~~ **an** exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or is no longer necessary.

"(iii) CONSIDERATIONS.—

"(I) IN GENERAL.—Subject to subclause (II), the Administrator shall issue exemptions and establish time periods by considering factors determined by the Administrator to be relevant to the goals of fostering innovation and the development of alternatives that meet the safety standard.

"(II) LIMITATION.—Any renewal of an exemption in the case of a rule **under paragraph (1)** requiring the ban or phase-out of a chemical substance shall not exceed 5 years.

"(e) Immediate Effect.—The Administrator may declare a proposed rule under subsection (d)(1) to be effective on publication of the rule in the Federal Register and until the effective date of final action taken respecting the rule, if—

"(1) the Administrator determines that—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to the proposed rule or any combination of those activities is likely to result in a risk of serious or widespread injury to health or the environment before the effective date; and

"(B) making the proposed rule so effective is necessary to protect the public interest; and

"(2) in the case of a proposed rule to prohibit the manufacture, processing, or distribution in commerce of a chemical substance or mixture because of the risk determined under paragraph (1)(A), a court has granted relief in an action under section 7 with respect to that risk associated with the chemical substance or mixture.

"(f) Final Agency Action.—Under this section and subject to section 18—

"(1) a safety determination, and the associated safety assessment, for a chemical substance that the Administrator determines under subsection (c) meets the safety standard, shall be considered to be a final agency action, effective beginning on the date of issuance of the final safety determination; and

"(2) a final rule promulgated under subsection (d)(1), and the associated safety assessment and safety determination that a chemical substance does not meet the safety

Commented [A11]: This may create confusion about the safety standard, since the point of a critical use exemption is that the standard will not be met. An earlier draft added "to the extent practicable" to address this issue.

Commented [A12]: Per previous comments, this makes no sense.

standard, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final ~~rule.";~~ **rule.**

~~(4) in subsection (g)~~**"(g) Extension of Deadlines for Certain Chemical Substances.—The Administrator may not extend any deadline under subsection (a) for a chemical substance designated as a high priority that is listed in the 2014 update of the TSCA Work Plan without adequate public justification that demonstrates, following a review of the information reasonably available to the Administrator, that the Administrator cannot adequately complete a safety assessment and safety determination, or a final rule pursuant to subsection (d), without additional information regarding the chemical substance."; and**

(4) in subsection (h) (as redesignated by paragraph (2))—

(A) by striking paragraph (4); and

(B) by redesignating paragraph (5) as paragraph (4).

SEC. 9. IMMINENT HAZARDS.

Section 7 of the Toxic Substances Control Act (15 U.S.C. 2606) is amended—

(1) by striking subsection (a) and inserting the following:

"(a) Civil Actions.—

"(1) IN GENERAL.—The Administrator may commence a civil action in an appropriate United States district court for—

"(A) seizure of an imminently hazardous chemical substance or mixture or any article containing the chemical substance or mixture;

"(B) relief (as authorized by subsection (b)) against any person that manufactures, processes, distributes in commerce, uses, or disposes of, an imminently hazardous chemical substance or mixture or any article containing the chemical substance or mixture; or

"(C) both seizure described in subparagraph (A) and relief described in subparagraph (B).

"(2) RULE, ORDER, OR OTHER PROCEEDING.—A civil action may be commenced under this paragraph, notwithstanding—

"(A) the existence of a decision, rule, consent agreement, or order by the Administrator under section 4, 4A, 5, or 6 or title IV or VI; or

"(B) the pendency of any administrative or judicial proceeding under any provision of this Act.";

(2) in subsection (b)(1), by striking "unreasonable";

(3) in subsection (d), by striking "section 6(a)" and inserting "section 6(d)"; and

(4) in subsection (f), in the first sentence, by striking "and unreasonable".

SEC. 10. INFORMATION COLLECTION AND REPORTING.

Section 8 of the Toxic Substances Control Act (15 U.S.C. 2607) is amended—

(1) in subsection (a)—

(A) in paragraph ~~(3)~~**(3)—**

(i) in subparagraph (A)(ii)(I)—

~~(i)~~**(I)** by striking "5(b)(4)" and inserting "5";

~~(ii)~~**(II)** by inserting "section 4 or" after "in effect under"; and

~~(iii)~~**(III)** by striking "5(e)," and inserting "5(d)(4);"; and

(ii) by adding at the end the following:

"(C) Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and not less frequently than once every 10 years thereafter, the Administrator, after consultation with the Administrator of the Small Business Administration, shall—

"(i) review the adequacy of the standards prescribed according to subparagraph (B);

"(ii) after providing public notice and an opportunity for comment, make a determination as to whether revision of the standards is warranted; and

"(iii) revise the standards if the Administrator so determines."; and

(B) by adding at the end the following:

"(4) RULES.—

"(A) DEADLINE.—

"(i) IN GENERAL.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall promulgate rules requiring the maintenance of records and the reporting of **additional** information known or reasonably ascertainable by the person making the report, including rules ~~requiring~~ **applicable to** processors ~~to report information,~~ so that the Administrator has the information necessary to carry out ~~sections 4 and 6~~ **this title**.

"(ii) MODIFICATION OF PRIOR RULES.—In carrying out this subparagraph, the Administrator may modify, as appropriate, rules promulgated before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(B) CONTENTS.—The rules promulgated pursuant to subparagraph (A)—

"(i) may impose different reporting and recordkeeping requirements on manufacturers and processors; and

"(ii) shall include the level of detail necessary to be reported, including the manner by which use and exposure information may be reported.

"(C) ADMINISTRATION.—In implementing the reporting and recordkeeping requirements under this paragraph, the Administrator shall take measures—

"(i) to limit the potential for duplication in reporting requirements;

Commented [A13]: This mandatory periodic review, including two comment periods, will likely have little or no value, since the new 8(a)(4) authority allows EPA to collect anything it could collect under 8(a)(1), with no small business exemption.

"(ii) to minimize the impact of the rules on small manufacturers and processors; and

"(iii) to apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this **title.";** ~~title.~~

~~"(5) Guidance.—The Administrator shall develop guidance relating to the information required to be reported under the rules promulgated under this subsection.";~~

(2) in subsection (b), by adding at the end the following:

"(3) NOMENCLATURE.—

"(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

"(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

"(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and

"(iii) treat all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation—

"(I) cement, Portland, chemicals, CAS No. 65997–15–1;

"(II) cement, alumina, chemicals, CAS No. 65997–16–2;

"(III) glass, oxide, chemicals, CAS No. 65997–17–3;

"(IV) frits, chemicals, CAS No. 65997–18–4;

"(V) steel manufacture, chemicals, CAS No. 65997–19–5; and

"(VI) ceramic materials and wares, chemicals, CAS No. 66402–68–4.

"(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

"(i) IN GENERAL.—If an existing guidance allows for multiple nomenclature conventions, the Administrator shall—

"(I) maintain the nomenclature conventions for substances; and

"(II) develop new guidance that—

"(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and

"(bb) permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1).

Commented [A14]: This phrase strikes us as imprecise. The following would be clearer: "all chemical substances described by the following category listings, when manufactured as described in Appendix A of column I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA-560/7-85-002a)"

Commented [A15]: We are not aware of any "statutory mixtures" beyond the six listed, so we think it is unclear what else might be contemplated.

Commented [A16]: We assume that this refers only to EPA guidance, and suggest clarification. Additionally, EPA is unaware of any existing EPA guidance that allow for multiple nomenclature conventions, meaning that these provisions would have a null effect.

"(ii) MULTIPLE CAS NUMBERS.—For any chemical substance appearing multiple times on the list under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.

"(4) CHEMICAL SUBSTANCES IN COMMERCE.—

"(A) RULES.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator, by rule, shall require manufacturers and processors to notify the Administrator, by not later than 180 days after the date of promulgation of the rule, of each chemical substance on the list published under paragraph (1) that the manufacturer or processor, as applicable, has manufactured or processed for a nonexempt commercial purpose during the 10-year period ending on the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(ii) ACTIVE SUBSTANCES.—The Administrator shall~~, pursuant to paragraph (5)(A),~~ designate chemical substances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

"(iii) INACTIVE SUBSTANCES.—The Administrator shall designate chemical substances for which no notices are received under clause (i) to be inactive substances on the list published under paragraph (1).

"(B) CONFIDENTIAL CHEMICAL ~~SUBSTANCES.—THE RULE PROMULGATED BY THE ADMINISTRATOR~~ SUBSTANCES.—**In promulgating the rule established** pursuant to subparagraph (A) ~~shall require—~~**, the Administrator shall—**

~~"(i) the Administrator to~~**"(i)** maintain the list under paragraph (1), which shall include a confidential portion and a nonconfidential portion consistent with this section and section 14;

"(ii) **require** a manufacturer or processor that is submitting a notice pursuant to subparagraph (A) for a chemical substance on the confidential portion of the list published under paragraph (1) to indicate in the notice whether the manufacturer or processor seeks to maintain any existing claim for protection against disclosure of the specific identity of the substance as confidential pursuant to section 14; and

"(iii) **require** the substantiation of those claims pursuant to section 14 and in accordance with the review plan described in subparagraph (C).

"(C) REVIEW PLAN.—Not later than 1 year after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A), the Administrator shall promulgate a rule that establishes a plan to review all claims to protect the specific identities of chemical substances on the confidential portion of the list published under paragraph (1) that are ~~notified~~ **asserted** pursuant to subparagraph ~~(A) or identified as active substances under subsection (f)(1).~~**(B).**

"(D) REQUIREMENTS OF REVIEW ~~PLAN.—THE~~ PLAN.—**Under the** review plan under subparagraph (C)**, the Administrator** shall—

"(i) require, at the time requested by the Administrator, all manufacturers or processors asserting claims under subparagraph (B) to substantiate the claim unless the manufacturer or processor has substantiated the claim in a submission made to the Administrator during the 5-year period ending on the date of the request by the Administrator;

"(ii) ~~require the Administrator,~~ in accordance with section 14—

"(I) ~~to~~ review each substantiation—

"(aa) submitted pursuant to clause (i) to determine if the claim warrants protection from disclosure; and

"(bb) submitted previously by a manufacturer or processor and relied on in lieu of the substantiation required pursuant to clause (i), if the substantiation has not been previously reviewed by the Administrator, to determine if the claim warrants protection from disclosure;

"(II) approve, modify, or deny each claim; and

Commented [A17]: It is confusing to refer to EPA "modifying," the claims of a 3rd party. EPA can't change the fact that some 3rd party claims something, but the intent here seems to be to allow EPA to approve a subset of the full claim. It would be clearer to refer to say: "approve, approve in part, or deny"

"(III) except as provided in this section and section 14, protect from disclosure information for which the Administrator approves such a claim for a period of 10 years, unless, prior to the expiration of the period—

"(aa) the person notifies the Administrator that the person is withdrawing the ~~confidentiality~~ claim, in which case the Administrator shall promptly make the information available to the public; or

"(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

"(iii) encourage manufacturers or processors that have previously made claims to protect the specific identities of chemical substances identified as inactive pursuant to subsection (f)(2) to review and either withdraw or substantiate the claims.

Commented [A18]: "And" is probably clearer here, to avoid suggesting that this is an exclusive or... goal is to encourage both manufacturers and processors.

"(E) TIMELINE FOR COMPLETION OF REVIEWS.—

"(i) IN GENERAL.—The Administrator shall implement the review plan so as to complete reviews of all claims specified in subparagraph (C) not later than 5 years after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A).

"(ii) CONSIDERATIONS.—

"(I) IN GENERAL.—The Administrator may extend the deadline for completion of the reviews for not more than 2 additional years, after an adequate public justification, if the Administrator determines that the extension is necessary based on the number of ~~applicable~~ claims needing review and the available resources.

"(II) ANNUAL ~~GOAL.—THE~~ REVIEW GOAL AND RESULTS.—**At the**

beginning of each year, the Administrator shall publish an annual goal for **reviews and** the number of reviews ~~to be completed over the course of implementation of the plan.~~ **completed in the prior year.**

"(5) ACTIVE AND INACTIVE SUBSTANCES.—

"(A) IN GENERAL.—The Administrator shall maintain and keep current designations of active substances and inactive substances on the list published under paragraph (1).

"(B) ~~UPDATE.—THE ADMINISTRATOR SHALL UPDATE THE LIST OF CHEMICAL SUBSTANCES DESIGNATED AS ACTIVE SUBSTANCES AS SOON AS PRACTICABLE AFTER THE DATE OF PUBLICATION OF THE MOST RECENT DATA REPORTED UNDER—~~

~~"(I) PART 711 OF TITLE 40, CODE OF FEDERAL REGULATIONS (OR SUCCESSOR REGULATIONS); AND~~

~~"(II) THE RULES PROMULGATED PURSUANT TO SUBSECTION (A)(4).~~

~~"(C)~~ CHANGE TO ACTIVE STATUS.—

"(i) IN GENERAL.—Any person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive substance shall notify the Administrator before the date on which the inactive substance is manufactured or processed.

"(ii) CONFIDENTIAL CHEMICAL IDENTITY CLAIMS.—If a person submitting a notice under clause (i) for an inactive substance on the confidential portion of the list published under paragraph (1) seeks to maintain an existing claim for protection against disclosure of the specific identity of the inactive substance as confidential, the person shall—

"(I) in the notice submitted under clause (i), assert the claim; and

"(II) by not later than 30 days after providing the notice under clause (i), substantiate the claim.

"(iii) ACTIVE STATUS.—On receiving a notification under clause (i), the Administrator shall—

"(I) designate the applicable chemical substance as an active substance;

"(II) pursuant to section 14, promptly review any claim and associated substantiation submitted pursuant to clause (ii) for protection against disclosure of the specific identity of the chemical substance and approve, modify, or deny the claim;

"(III) except as provided in this section and section 14, protect from disclosure the specific identity of the chemical substance for which the Administrator approves a claim under subclause (II) for a period of ~~not less than~~ 10 years, unless, prior to the expiration of the period—

"(aa) the person notifies the Administrator that the person is withdrawing the ~~confidentiality~~ claim, in which case the Administrator shall promptly make the information available to the public; or

"(bb) the Administrator otherwise becomes aware that the need for

Commented [A19]: Unlike other provisions of the bill under which EPA is given authority to specify the manner of CBI assertion and substantiation, there is no such authority here. If the intent is for EPA to have such authority, it could be added.

Commented [A20]: It is confusing to refer to EPA "modifying," the claims of a 3rd party. EPA can't change the fact that some 3rd party claims something, but the intent here seems to be to allow EPA to approve a subset of the full claim. It would be clearer to refer to say: "approve, approve in part, or deny"

protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

"(IV) pursuant to section 4A, review the priority of the chemical substance as the Administrator determines to be necessary.

~~"(D)~~**"(C)** CATEGORY STATUS.—The list of inactive substances shall not be considered to be a category for purposes of section 26(c).

"(6) INTERIM LIST OF ACTIVE SUBSTANCES.—Prior to the promulgation of the rule required under paragraph (4)(A), the Administrator shall designate the chemical substances reported under part 711 of title 40, Code of Federal Regulations ~~(or successor regulations)~~**(as in effect on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act)**, during the reporting period that most closely preceded the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as the interim list of active substances for the purposes of section 4A.

"(7) PUBLIC ~~PARTICIPATION.—SUBJECT~~ INFORMATION.—**Subject** to this subsection, the Administrator shall make available to the public—

"(A) the specific identity of each chemical substance on the nonconfidential portion of the list published under paragraph (1) that the Administrator has designated as—

"(i) an active substance; or

"(ii) an inactive substance;

"(B) the accession number, generic name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the list published under paragraph (1) for which a claim of confidentiality was received ~~and approved by the Administrator pursuant to section 14~~; and

"(C) subject to **subsections (f) and (g) of** section 14~~(g)~~, the specific identity of any active substance for which—

"(i) ~~no~~ **a** claim ~~of~~ **for** protection against disclosure of the specific identity of the active ~~substance pursuant to this subsection was received~~**, chemical substance was not asserted, as required under this subsection or subsection (d) or (f) of section 14;**

Commented [A21]: Should be stricken. The defined term is "active substance".

"(ii) a claim for protection against disclosure of the specific identity of the active substance has been denied by the Administrator; or

"(iii) the time period for protection against disclosure of the specific identity of the active substance has expired.

"(8) LIMITATION.—No person may assert a new claim under this subsection for protection from disclosure of a specific identity of any active or inactive chemical substance for which a notice is received under paragraph (4)(A)(i) or (5)(C)(i) that is not on the confidential portion of the list published under paragraph (1).

Commented [A22]: Same comment

"(9) CERTIFICATION.—Under the rules promulgated under this subsection, manufacturers and processors shall be required—

"(A) to certify that each ~~report~~ **notice or substantiation** the manufacturer or processor submits complies with the requirements of the rule, and that any confidentiality claims are true and correct; and

"(B) to retain a record supporting the certification for a period of 5 years beginning on the last day of the submission period.";

(3) in subsection (e)—

(A) by striking "Any person" and inserting the following:

"(1) IN GENERAL.—Any person"; and

(B) by adding at the end the following:

"(2) ~~APPLICABILITY.—ANY~~ **ADDITIONAL INFORMATION.—Any** person may submit to the Administrator information reasonably supporting the conclusion that a chemical substance or mixture presents, will present, or does not present a substantial risk of injury to health and the environment."; and

(4) in subsection (f), by striking "For purposes of this section, the" and inserting the following: "In this section:

"(1) ACTIVE SUBSTANCE.—The term 'active substance' means a chemical substance—

"(A) that has been manufactured or processed for a nonexempt commercial purpose at any point during the 10-year period ending on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

"(B) that is added to the list published under subsection (b)(1) after that date of enactment; or

"(C) for which a notice is received under subsection (b)(5)(C).

"(2) INACTIVE SUBSTANCE.—The term 'inactive substance' means a chemical substance on the list published under subsection (b)(1) that does not meet any of the criteria described in paragraph (1).

"(3) MANUFACTURE; PROCESS.—The".

SEC. 11. RELATIONSHIP TO OTHER FEDERAL LAWS.

Section 9 of the Toxic Substances Control Act (15 U.S.C. 2608) is amended—

(1) in subsection (a)—

(A) in paragraph (1), in the first sentence—

(i) by striking "presents or will present an unreasonable risk to health or the environment" and inserting "does not **or will not** meet the safety standard"; and

(ii) by striking "such risk" the first place it appears and inserting "the risk posed by the substance or mixture";

(B) in paragraph ~~(2),~~**(2)—**

(i) in subparagraph (A), by inserting "within the time period specified by the Administrator in the report" after "issues an order";

(ii) in subparagraph (B), by inserting "responds within the time period specified by the Administrator in the report and" before "initiates, within 90 days"; and

(iii) in the matter following subparagraph (B), by striking "section 6 or 7" and inserting "section 6(d) or section 7";

~~and~~

~~(C) in~~**(C) by redesignating** paragraph (3) **as paragraph (6);**

(D) in paragraph (6) (as so redesignated), by striking "section 6 or 7" and inserting "section 6(d) or 7"; **and**

(E) by inserting after paragraph (2) the following:

"(3) The Administrator shall take the actions described in paragraph (4) if the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which the report was made does not—

"(A) issue the order described in paragraph (2)(A) within the time period specified by the Administrator in the report; or

"(B)(i) respond under paragraph (1) within the time frame specified by the Administrator in the report; and

"(ii) initiate action within 90 days of publication in the Federal Register of the response described in clause (i).

"(4) If an agency to which a report under paragraph (1) does not take the actions described in subparagraphs (A) or (B) of paragraph (3), the Administrator shall—

"(A) if a safety assessment and safety determination for the substance under section 6 has not been completed, complete the safety assessment and safety determination;

"(B) if the Administrator has determined or determines that the chemical substance does not meet the safety standard, initiate action under section 6(d) with respect to the risk; or

"(C) take any action authorized or required under section 7, as appropriate.

"(5) This subsection shall not relieve the Administrator of any obligation to complete a safety assessment and safety determination or take any required action under section 6(d) or 7 to address risks from the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or any combination of those activities, that are not identified in a report issued by the Administrator under paragraph (1).";

(2) in subsection (d), in the first sentence, by striking "Health, Education, and Welfare" and inserting "Health and Human Services"; and

(3) by adding at the end the following:

"(e) Exposure Information.—If the Administrator obtains information related to exposures or releases of a chemical substance that may be prevented or reduced under another Federal law,

including laws not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency.".

SEC. 12. RESEARCH, DEVELOPMENT, COLLECTION, DISSEMINATION, AND UTILIZATION OF DATA.

Section 10 of the Toxic Substances Control Act (15 U.S.C. 2609) is amended by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services".

SEC. 13. EXPORTS.

Section 12 of the Toxic Substances Control Act (15 U.S.C. 2611) is amended—

(1) in subsection (a), by striking paragraph (2) and inserting the following:

"(2) EXCEPTION.—Paragraph (1) shall not apply ~~to~~ **to—**

"(A) any **new** chemical substance that the Administrator ~~determines—~~ **determines is likely to present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors;**

~~"(A) under section 5 is not likely to meet the safety standard; or~~**"(B) any chemical substance that the Administrator determines presents or will present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors; or**

~~"(B) under section 6 does not meet the safety standard.~~**"(C) any chemical substance that—**

~~"(3) Waivers.—For~~**"(i) the Administrator determines is likely to present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors; and**

"(ii) is subject to restriction under section 5(d)(4).

"(3) WAIVERS FOR CERTAIN MIXTURES AND ARTICLES.—For a mixture or article containing a chemical substance described in paragraph (2), the Administrator may—

"(A) determine that paragraph (1) shall not apply to the mixture or article; or

"(B) establish a threshold concentration in a mixture or article at which paragraph (1) shall not apply.

"(4) TESTING.—The Administrator may require testing under section 4 of any chemical substance or mixture exempted from this Act under paragraph (1) for the purpose of determining whether the chemical substance ~~or mixture~~ meets the safety standard within the United States.";

Commented [A23]: Should be "presents an unreasonable risk", consistent with (a)(2) language above.

(2) by striking subsection (b) and inserting the following:

"(b) Notice.—

"(1) IN GENERAL.—A person shall notify the Administrator that the person is exporting or intends to export to a foreign country—

"(A) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 5 is not likely to meet the safety standard and for which a prohibition or other restriction has been proposed or established under that section;

"(B) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 6 does not meet the safety standard and for which a prohibition or other restriction has been proposed or established under that section;

"(C) a chemical substance for which the United States is obligated by treaty to provide export notification;

"(D) a chemical substance or mixture **containing a chemical substance** subject to a **proposed or promulgated** significant new use rule, or a prohibition or other restriction pursuant to a rule, order, or consent agreement in effect under this Act; ~~or~~

"(E) a chemical substance or mixture for which the submission of information is required under section 4**; or**

"(F) a chemical substance or mixture for which an action is pending or for which relief has been granted under section 7.~~;~~

"(2) RULES.—

"(A) IN GENERAL.—The Administrator shall promulgate rules to carry out paragraph (1).

"(B) CONTENTS.—The rules promulgated pursuant to subparagraph (A) shall—

"(i) include such exemptions as the Administrator determines to be appropriate, which may include exemptions identified under section 5(h); and

"(ii) indicate whether, or to what extent, the rules apply to articles containing a chemical substance or mixture described in paragraph (1).

"(3) NOTIFICATION.—The Administrator shall submit to the government of each country to which a chemical substance or mixture is exported—

"(A) for a chemical substance or mixture described in subparagraph (A), (B), ~~or~~(D)**, or (F)** of paragraph (1), a notice of the determination, rule, order, consent agreement, **action, relief, or** requirement~~, or designation~~;

"(B) for a chemical substance described in paragraph (1)(C), a notice that satisfies the obligation of the United States under the applicable treaty; and

"(C) for a chemical substance or mixture described in paragraph (1)(E), a notice of availability of the information on the chemical substance or mixture submitted to the Administrator."; and

(3) in subsection **(c),**~~(c)—~~

~~(A)~~ by striking paragraph (3)~~; and~~

~~(B) by redesignating paragraphs (4) through (6) as paragraphs (3) through (5), respectively~~.

SEC. 14. CONFIDENTIAL INFORMATION.

Section 14 of the Toxic Substances Control Act (15 U.S.C. 2613) is amended to read as follows:

"SEC. 14. CONFIDENTIAL INFORMATION.

"(a) In General.—Except as otherwise provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, under subsection (b)(4) of that section—

"(1) that is reported to, or otherwise obtained by, the Administrator under this Act; and

"(2) for which the requirements of subsection (d) are met.

"(b) Information Generally Protected From Disclosure.—The following information specific to, and submitted by, a manufacturer, processor, or distributor that meets the requirements of subsections (a) and (d) shall be presumed to be protected from disclosure, subject to the condition that nothing in this Act prohibits the disclosure of any such information, or information that is the subject of subsection (g)(3), through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law:

"(1) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

"(2) Marketing and sales information.

"(3) Information identifying a supplier or customer.

"(4) Details of the full composition of a mixture and the respective percentages of constituents.

"(5) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or product.

"(6) Specific production or import volumes of the manufacturer ~~and specific~~.

"(7) Specific aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

~~"(7)~~**"(8)** Except as otherwise provided in this section, the specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, **if** ~~if—~~

~~"(A)~~ the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5~~; and~~

~~"(B) the claim—~~

Commented [A24]: As we have previously pointed out, it makes no sense to condition presumptive protection on whether the information actually meets the CBI standard in (a). In addition, this may increase the number of CBI claims EPA must review, since EPA may not be able treat information as falling under (b) and hence not subject to review without first determining it is CBI.

Commented [A25]: As we have previously pointed out, this proviso for *presumptive* CBI suggests that other CBI will be shielded from discovery, etc.

Commented [A26]: The point of this provision presumably is to protect chem id in advance of an NOC, but some pre-NOC distribution would likely be considered offered for commercial distribution under TSCA (e.g., distribution for R&D).

Conversely, some post-NOC manufacturing, processing, and distribution might not qualify as "offer[ing]" the chemical to another party, and so arguably might not fall under this heading.

~~"(i) is not subject to an exception under subsection (e); or~~

~~"(ii) has not subsequently been withdrawn or found by the Administrator not to warrant protection as confidential information under subsection (f)(2) or (g).~~

"(c) Information Not Protected From ~~Disclosure.—Notwithstanding~~ **Disclosure.—**

"(1) IN GENERAL.—Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:

~~"(1)~~**"(A)** INFORMATION FROM HEALTH AND SAFETY STUDIES.—

~~"(A)~~**"(i)** IN GENERAL.—Subject to ~~subparagraph (B), subsection (a) does not prohibit the disclosure of~~ **clause (ii)—**

~~"(i)~~**"(I)** any health and safety study that is submitted under this Act with respect to—

~~"(I)~~**"(aa)** any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

~~"(II)~~**"(bb)** any chemical substance or mixture for which—

~~"(aa)~~**"(AA)** testing is required under section 4; or

~~"(bb)~~**"(BB)** a notification is required under section 5; or

~~"(ii)~~**"(II)** any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in ~~subclause (I) or (II) of clause (i).~~ **item (aa) or (bb) of subclause (I).**

~~"(B)~~**"(ii)** EFFECT OF ~~PARAGRAPH.—NOTHING~~ SUBPARAGRAPH.—**Nothing** in this ~~paragraph~~ **subparagraph** authorizes the release of any information that discloses—

~~"(i)~~**"(I)** a process used in the manufacturing or processing of a chemical substance or mixture; or

~~"(ii)~~**"(II)** in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

~~* 4 "(2) Certain requests.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is described in paragraph (1) that is not described in paragraph (1)(B), the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.~~

~~"(3)~~**"(B)** OTHER INFORMATION NOT PROTECTED FROM ~~DISCLOSURE.—THE FOLLOWING INFORMATION IS NOT PROTECTED FROM DISCLOSURE UNDER THIS SECTION:~~ **DISCLOSURE.—**

~~"(A)~~**"(i)** For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered

for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

Commented [A27]: As we have previously pointed out, this adds nothing and could create confusion, since the point it makes for specific chem id is true for all information – ie, it cannot be CBI if not properly claimed.

~~"(B)~~**"(ii)** A safety assessment developed, or a safety determination made, under section 6.

~~"(C)~~**"(iii)** Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

~~"(D)~~**"(iv)** A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

~~"(4)~~**"(2)** MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION .—Any information that is ~~otherwise~~ eligible for protection under this section and ~~contained in a submission of~~ **is submitted with** information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

~~"(5)~~**"(3)** BAN OR PHASE-OUT.—If the Administrator promulgates a rule pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance, subject to paragraphs (2), (3), and (4) of subsection (g), any protection from disclosure provided under this section with respect to the specific identity of the chemical substance and other information relating to the chemical substance shall no longer apply.

** **4** ~~"(2)~~**"(4)** CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is ~~described in paragraph (1) that is not described in paragraph (1)(B)~~ **subject to disclosure under this subsection**, the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

"(d) Requirements for Confidentiality Claims.—

"(1) ASSERTION OF CLAIMS.—

"(A) IN GENERAL.—A person seeking to protect any information submitted under this Act from disclosure (including information described in subsection (b)) shall assert to the Administrator a claim for protection concurrent with submission of the information, in accordance with such rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this title.

"(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—

"(i) taken reasonable measures to protect the confidentiality of the information;

"(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

"(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

"(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

"(C) SPECIFIC CHEMICAL IDENTITY.—In the case of a claim under subparagraph (A) for protection against disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that the generic name shall—

"(i) ~~conform~~ **be consistent** with guidance ~~prescribed~~ **issued** by the Administrator under paragraph (3)(A); and

"(ii) describe the chemical structure of the substance as specifically as practicable while protecting those features of the chemical structure—

"(I) that are considered to be confidential; and

"(II) the disclosure of which would be likely to **cause substantial** harm **to** the competitive position of the person.

"(D) PUBLIC INFORMATION.—No person may assert a claim under this section for protection from disclosure of information that is already publicly available.

"(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—Except for information described in ~~paragraphs (1) through (7) of~~ subsection (b), a person asserting a claim to protect information from disclosure under this Act shall substantiate the claim, in accordance with the rules promulgated and **consistent with the** guidance issued by the Administrator.

"(3) GUIDANCE.—The Administrator shall develop guidance regarding—

"(A) the determination of structurally descriptive generic names, in the case of claims for the protection against disclosure of specific chemical identity; and

"(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (e).

"(4) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the ~~information that has been submitted is~~ **statement required to assert a claim submitted pursuant to paragraph (1)(B) and any information required to substantiate a claim submitted pursuant to paragraph (2) are** true and correct.

"(e) Exceptions to Protection From Disclosure.—Information described in subsection (a)—

"(1) shall be disclosed if the information is to be disclosed to an officer or employee of the United States in connection with the official duties of the officer or employee—

"(A) under any law for the protection of health or the environment; or

"(B) for a specific law enforcement purpose;

"(2) shall be disclosed if the information is to be disclosed to a contractor of the United States and employees of that contractor—

"(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act; and

"(B) subject to such conditions as the Administrator may specify;

"(3) shall be disclosed if the Administrator determines that disclosure is necessary to protect health or the environment;

"(4) shall be disclosed if the information is to be disclosed to a State or political subdivision of a State, on written request, for the purpose of development, administration, or enforcement of a law, **if** ~~if—~~

~~"(A)~~ 1 or more applicable agreements with the Administrator that ~~conform~~ **are consistent** with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information; ~~and~~

~~"(B) the Administrator notifies the person that submitted the information that the information has been disclosed to the State or political subdivision of a State;~~

"(5) shall be disclosed if a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

"(A) the statement of need and confidentiality agreement ~~shall conform~~ **are consistent** with the guidance issued under subsection (d)(3)(B);

"(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

"(i) the information is necessary for, or will assist in—

"(I) the diagnosis or treatment of 1 or more individuals; or

"(II) responding to an environmental release or exposure; and

"(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

"(C) the confidentiality agreement shall provide that the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

"(6) shall be disclosed if in the event of an emergency, a treating physician, nurse, agent

of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder (including any individual duly authorized by a Federal agency, State, or political subdivision of a State who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) requests the information, subject to the conditions that—

"(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable basis to suspect that—

"(i) a medical or public health or environmental emergency exists;

"(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

"(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred;

"(B) if requested by the person submitting the information to the Administrator, the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

"(i) provide a written statement of need; and

"(ii) agree to sign a confidentiality agreement; and

"(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed;

"(7) may be disclosed if the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure shall be made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding;

"(8) shall be disclosed if the information is to be disclosed, on written request of any duly authorized congressional committee, to that committee; or

"(9) shall be disclosed if the information is required to be disclosed or otherwise made public under any other provision of Federal law.

"(f) Duration of Protection From Disclosure.—

"(1) IN GENERAL.—

"(A) INFORMATION ~~PROTECTED~~ **NOT SUBJECT TO TIME LIMIT FOR PROTECTION** FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information **described in subsection (b)** that meets the requirements of ~~subsection (d) for a period of 10 years, unless, prior to the expiration of the period—~~ **subsections (a) and (d), unless—**

~~"(i) an affected person~~ **"(i) the person that asserted the claim** notifies the Administrator that the person is withdrawing the ~~confidentiality~~ claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the ~~need for protection from disclosure can no longer be substantiated~~ **information does not qualify or no longer qualifies for protection against disclosure under subsection (a)**, in which case the Administrator shall take ~~the~~ **any** actions ~~described in~~ **required under** subsection (g)(2).

"(B) **INFORMATION SUBJECT TO TIME LIMIT FOR PROTECTION FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information, other than information described in subsection (b), that meets the requirements of subsections (a) and (d) for a period of 10 years, unless, prior to the expiration of the period—**

"(i) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the information does not qualify or no longer qualifies for protection against disclosure under subsection (a), in which case the Administrator shall take any actions required under subsection (g)(2).

"(C) EXTENSIONS.—

"(i) IN GENERAL.—Not later than the date that is 60 days before the expiration of the period described in subparagraph ~~(A)~~**(B)**, the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

"(ii) STATEMENT.—

"(I) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in subparagraph ~~(A)~~**(B)**, a person reasserting the relevant claim shall submit to the Administrator a ~~statement~~ **request for extension** substantiating, in accordance with subsection (d)(2), the need to extend the period.

"(II) ACTION BY ADMINISTRATOR.—Not later than the date ~~that is 30 days after the date of receipt of a statement under subclause (I), the Administrator shall—~~ **of expiration of the period described in subparagraph (B), the Administrator shall, in accordance with subsection (g)(1)(C)—**

"(aa) review the request **submitted under subclause (I)**;

"(bb) make a determination regarding whether the ~~information~~ **claim** for which the request ~~is made~~ **was submitted** continues to meet the relevant criteria established under this section; and

"(cc)(AA) grant an extension of ~~not more than~~ 10 years; or

"(BB) deny the ~~claim.~~ **request.**

~~"(C)~~**"(D)** NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under subparagraph ~~(B)~~**(C)**, if the Administrator determines that the relevant ~~statement~~ **request** under subparagraph ~~(B)(ii)(I)~~—

(C)(ii)(I)—

"(i) establishes the need to extend the period; and

"(ii) meets the requirements established by the Administrator.

"(2) REVIEW AND RESUBSTANTIATION.—

"(A) DISCRETION OF ADMINISTRATOR.—The Administrator may review, at any time, a claim for protection **of information** against disclosure under subsection (a) ~~for information submitted to the Administrator regarding a chemical substance~~ and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) after the chemical substance is identified as a high-priority substance under section 4A;

"(ii) for any chemical substance for which the Administrator has made a determination under section 6(c)(1)(C);

"(iii) for any inactive chemical substance identified under section 8(b)(5); or

"(iv) in limited circumstances, if the Administrator determines that disclosure of certain information currently protected from disclosure would assist the Administrator in conducting safety assessments and safety determinations under subsections (b) and (c) of section 6 or promulgating rules pursuant to section 6(d)~~, subject to the condition that the information shall not be disclosed unless the claimant withdraws the claim or the Administrator determines that the information does not meet the requirements of subsection (d)~~.

Commented [A28]: Reference should be to 8(b)(5)(B) specifically – change to active status.

"(B) REVIEW REQUIRED.—The Administrator shall review a claim for protection ~~from~~ **of information against** disclosure under subsection (a) ~~for information submitted to the Administrator regarding a chemical substance~~ and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) as necessary to ~~comply~~ **determine whether the information qualifies for an exemption from disclosure in connection** with a request for information received by the Administrator under section 552 of title 5, United States Code;

"(ii) if ~~information available to the Administrator provides a basis that the requirements of section 552(b)(4) of title 5, United States Code, are no longer met;~~ **the Administrator has a reasonable basis to believe that the information does not qualify for protection against disclosure under subsection (a);** or

"(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

"(C) ACTION BY RECIPIENT.—If the Administrator makes a request under subparagraph (A) or (B), the recipient of the request shall—

"(i) reassert and substantiate or resubstantiate the claim; or

"(ii) withdraw the claim.

"(D) PERIOD OF PROTECTION.—Protection from disclosure of information subject to a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.

"(3) UNIQUE IDENTIFIER.—The Administrator shall—

"(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term; and

"(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

"(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to such a chemical substance during the period of protection from disclosure—

"(i) is made public; and

"(ii) identifies the chemical substance using the unique identifier; and

"(D) for each claim for protection of specific chemical identity that has been denied by the Administrator ~~on expiration of the period for appeal under subsection (g)(1), that has~~ **or** expired, or that has been withdrawn by the submitter, provide public access to the specific chemical identity clearly linked to all nonconfidential information received by the Administrator with respect to the chemical substance.

"(g) Duties of Administrator.—

"(1) DETERMINATION.—

"(A) IN GENERAL.—Except as provided in subsection (b), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (d), and not later than 30 days after the receipt of a request for extension of a claim under subsection (f), review and approve, modify, or deny the claim or request.

"(B) **REASONS FOR DENIAL OR MODIFICATION.—If the Administrator denies or modifies a claim or request under subparagraph (A)** ~~Denial or modification.—~~

~~"(i) In general.—Except as provided in subsections (c) and (f),~~ the Administrator shall **provide to the person that submitted the claim or request** ~~deny a claim to protect a chemical identity from disclosure only if the person that has submitted the claim fails to meet the requirements of subsections (a) and (d).~~

~~"(ii) Reasons for denial or modification.—The Administrator shall provide to a person that has submitted a claim described in clause (i)~~ a written statement of the reasons for the denial or modification of the claim **or request**.

Commented [A29]: It is confusing to refer to EPA "modifying," the claims of a 3rd party. EPA can't change the fact that some 3rd party claims something, but the intent here seems to be to allow EPA to approve a subset of the full claim. It would be clearer to refer to say: "approve, approve in part, or deny"

"(C) SUBSETS.—The Administrator shall—

"(i) except for claims described in subsection ~~(b)(7)~~**(b)(8)**, review all claims **or requests** under this section for the protection against disclosure of the specific identity of a chemical substance; and

"(ii) review a representative subset, comprising at least 25 percent, of all other claims **or requests** for protection against disclosure.

"(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim **or request** for protection against disclosure or extension under this section shall not be the basis for denial or elimination of a claim **or request** for protection against disclosure.

"(2) NOTIFICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (c), (e), and (f), if the Administrator denies or modifies a claim **or request** under paragraph (1), **intends to release information pursuant to subsection (e),** or promulgates a rule under section 6(d) establishing a ban or phase-out of a chemical substance, the Administrator shall notify, in writing and by certified mail, the person that submitted the claim of the intent of the Administrator to release the information.

Commented [A30]: This specifies three bases on which information claimed CBI might be released, but misses an important basis: where EPA determines protection is not warranted at some point during the protection period.

Commented [A31]: Certified mail is a cumbersome form of notification.

"(B) RELEASE OF INFORMATION.—**Except** ~~information.—~~

~~"(i) In general.—Except~~ as provided in ~~clause (ii)~~ **subparagraph (C)**, the Administrator shall not release information under this subsection until the date that is 30 days after the date on which the person that submitted the request receives notification under subparagraph (A).

~~"(ii)~~**"(C)** EXCEPTIONS.—

~~"(I)~~**"(i)** IN GENERAL.—For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim **or request** receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to health or the environment, in which case no prior notification shall be necessary.

"(ii) NOTIFICATION AS SOON AS PRACTICABLE.—For information under paragraphs (4) and (6) of subsection (e), the Administrator shall notify the person that submitted the information that the information has been disclosed as soon as practicable after disclosure of the information.

"(iii) NO NOTIFICATION REQUIRED.—Notification shall not be required—

"(I) for the disclosure of ~~"(II) No notification.—For~~ information under paragraph (1), (2), ~~(6),~~(7), or (9) of subsection (e)~~, no prior notification shall be necessary.~~**; or**

"(II) for the disclosure of information for which—

"(aa) a notice under subsection (f)(1)(C)(i) was received; and

"(bb) no request was received by the Administrator on or before

the date of expiration of the period for which protection from disclosure applies.

"(3) REBUTTABLE PRESUMPTION.—

"(A) IN GENERAL.—With respect to notifications provided by the Administrator ~~pursuant to subsection (c)(5)~~ **under paragraph (2) with respect to information pertaining to a chemical substance subject to a rule as described in subsection (c)(3)**, there shall be a rebuttable presumption that the public interest in disclosing confidential information related to a chemical substance subject to a rule promulgated under section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of the substance outweighs the proprietary interest in maintaining the protection from disclosure of that information.

"(B) REQUEST FOR NONDISCLOSURE.—A person that receives a notification under paragraph (2) with respect to the information described in subparagraph (A) may submit to the Administrator, before the date on which the information is to be released **pursuant to paragraph (2)(B)**, a request with supporting documentation describing why the person believes some or all of that information should not be disclosed.

"(C) DETERMINATION BY ADMINISTRATOR.—

"(i) IN GENERAL.—Not later than 30 days after the Administrator receives a request under subparagraph (B), the Administrator shall determine~~, at the discretion of the Administrator,~~ whether the documentation provided by the person making the request rebuts or does not rebut the presumption described in subparagraph (A), for all or a portion of the information that the person has requested not be disclosed.

"(ii) OBJECTIVE.—The Administrator shall make the determination with the objective of ensuring that information relevant to protection of health and the environment is disclosed to the maximum extent practicable.

"(D) TIMING.—Not later than 30 days after making the determination described in subparagraph (C), the Administrator shall make public the information the Administrator has determined is not to be protected from disclosure.

"(E) NO TIMELY REQUEST RECEIVED.—If the Administrator does not receive, before the date on which the information described in subparagraph (A) is to be released **pursuant to paragraph (2)(B)**, a request pursuant to subparagraph (B), the Administrator shall promptly make public all of the information.

"(4) APPEALS.—

"(A) IN GENERAL.—If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released **pursuant to paragraph (2)(B)**, the person may bring an action to restrain disclosure of the information in—

"(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

"(ii) the United States District Court for the District of Columbia.

"(B) NO DISCLOSURE.—The Administrator shall not disclose any information that is the subject of an appeal under this section before the date on which the applicable court rules on an action under subparagraph (A).

"(5) ~~ADMINISTRATION.—IN CARRYING OUT THIS SUBSECTION, THE ADMINISTRATOR SHALL USE THE PROCEDURES DESCRIBED IN PART 2 OF TITLE 40, CODE OF FEDERAL REGULATIONS (OR SUCCESSOR REGULATIONS).~~ **REQUEST AND NOTIFICATION SYSTEM.—The Administrator, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop a request and notification system that allows for expedient and swift access to information disclosed pursuant to paragraphs (5) and (6) of subsection (e) in a format and language that is readily accessible and understandable.**

"(h) Criminal Penalty for Wrongful Disclosure.—

"(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

"(A) IN GENERAL.—Subject to paragraph (2), a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—

"(i) by virtue of that employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a); and

"(ii) knowing that disclosure of that material is prohibited by subsection (a), willfully discloses the material in any manner to any person not entitled to receive that material.

"(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, making known of, or making available, information reported or otherwise obtained under this Act.

"(3) CONTRACTORS.—For purposes of this subsection, any contractor of the United States that is provided information in accordance with subsection (e)(2), including any employee of that contractor, shall be considered to be an employee of the United States.

"(i) Applicability.—

"(1) IN GENERAL.—Except as otherwise provided in this section, section 8, or any other applicable Federal law, the Administrator shall have no authority—

"(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information ~~submitted to~~ **reported to or otherwise obtained by** the Administrator under this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; or

"(B) to impose substantiation or resubstantiation requirements under this Act that are more extensive than those required under this section.

"(2) ~~PRIOR ACTIONS.—NOTHING~~ **ACTIONS PRIOR TO PROMULGATION OF RULES.—** **Nothing** in this Act prevents the Administrator from reviewing, requiring substantiation or resubstantiation for, or approving, modifying or denying any claim for the protection from disclosure of information before the effective date of such rules applicable to those claims as the Administrator may promulgate after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

Commented [A32]: It is confusing to refer to EPA "modifying," the claims of a 3rd party. EPA can't change the fact that some 3rd party claims something, but the intent here seems to be to allow EPA to approve a subset of the full claim. It would be clearer to refer to say: "approving, approving in part, or denying"

SEC. 15. PROHIBITED ACTS.

Section 15 of the Toxic Substances Control Act (15 U.S.C. 2614) is amended by striking paragraph (1) and inserting the following:

"(1) fail or refuse to comply with—

"(A) any rule promulgated, consent agreement entered into, or order issued under section 4;

"(B) any requirement under section 5 or 6;

"(C) any rule promulgated, consent agreement entered into, or order issued under section 5 or 6; or

"(D) any requirement of, or any rule promulgated or order issued pursuant to title II;".

SEC. 16. PENALTIES.

Section 16 of the Toxic Substances Control Act (15 U.S.C. 2615) is amended—

(1) in subsection (a)(1)—

(A) in the first **sentence,** ~~sentence—~~

~~(i) by inserting "this Act or a rule or order promulgated or issued pursuant to this Act, including" after "a provision of"; and~~

~~(ii)~~ by striking "$25,000" and inserting "$37,500"; and

(B) in the second sentence, by striking" violation of section 15 or 409" and inserting "violation of this Act"; and

(2) in subsection (b)—

(A) by striking "Any person who" and inserting the following:

"(1) IN GENERAL.—Any person that";

(B) ~~by striking "section 15 or 409" and inserting "this Act";~~

~~(C)~~ by striking "$25,000" and inserting "$50,000"; and

~~(D)~~**(C)** by adding at the end the following:

"(2) IMMINENT DANGER OF DEATH OR SERIOUS BODILY INJURY.—

"(A) IN GENERAL.—Any person that knowingly or willfully violates any provision of ~~this Act~~ **section 15 or 409**, and that knows at the time of the violation that the violation places an individual in imminent danger of death or serious bodily injury, shall be

subject on conviction to a fine of not more than $250,000, or imprisonment for not more than 15 years, or both.

"(B) ORGANIZATIONS.—An organization that commits a violation described in subparagraph (A) shall be subject on conviction to a fine of not more than $1,000,000 for each violation.

~~"(3) Knowledge of imminent danger or injury.—For purposes of determining whether a defendant knew that the violation placed another individual in imminent danger of death or serious bodily injury—~~

~~"(A) the defendant shall be responsible only for actual awareness or actual belief possessed; and~~

~~"(B) knowledge possessed by an individual may not be attributed to the defendant.".~~**"(C) INCORPORATION OF CORRESPONDING PROVISIONS.—Subparagraphs (B) through (F) of section 113(c)(5) of the Clean Air Act (42 U.S.C. 7413(c)(5)) shall apply to the prosecution of a violation under this paragraph.".**

SEC. 17. STATE-FEDERAL RELATIONSHIP.

Section 18 of the Toxic Substances Control Act (15 U.S.C. 2617) is amended by striking subsections (a) and (b) and inserting the following:

"(a) In General.—

"(1) ESTABLISHMENT OR ENFORCEMENT.—Except as provided in subsections (c), (d), (e), (f), and (g), and subject to paragraph (2), no State or political subdivision of a State may establish or continue to enforce any of the following:

"(A) ~~TESTING AND INFORMATION COLLECTION.—A~~ **TESTING.—A** statute or administrative action to require the development of information on a chemical substance or category of substances that is reasonably likely to produce the same information required under section 4, 5, or 6 in—

"(i) a rule promulgated by the Administrator;

"(ii) a testing consent agreement entered into by the Administrator; or

"(iii) an order issued by the Administrator.

"(B) CHEMICAL SUBSTANCES FOUND TO MEET THE SAFETY STANDARD OR RESTRICTED.—A statute or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

"(i) found to meet the safety standard and consistent with the scope of the determination made under section 6; or

"(ii) found not to meet the safety standard, after the effective date of the rule issued under section 6(d) for the substance, consistent with the scope of the determination made by the Administrator.

"(C) SIGNIFICANT NEW USE.—A statute or administrative action requiring the notification of a use of a chemical substance that the Administrator has specified as a

significant new use and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

"(2) EFFECTIVE DATE OF PREEMPTION.—Under this subsection, Federal preemption of ~~State~~ statutes and administrative actions applicable to specific substances shall not occur until the effective date of the applicable action described in paragraph (1) taken by the Administrator.

"(b) New Statutes or Administrative Actions Creating Prohibitions or Other Restrictions.—

"(1) IN GENERAL.—Except as provided in subsections (c), (d), ~~and~~(e), **(f), and (g),** beginning on the date on which the Administrator defines **and publishes** the scope of a safety assessment and safety determination under section 6(a)(2) and ending on the date on which the **deadline established pursuant to section 6(a) for completion of the safety determination expires, or on the date on which the** Administrator publishes the safety determination **under section 6(a), whichever is earlier**, no State or political subdivision of a State may establish a statute or administrative action prohibiting or restricting the manufacture, processing, distribution in commerce or use of a chemical substance that is a high-priority substance designated under section 4A.

"(2) EFFECT OF SUBSECTION.—

"(A) IN GENERAL.—This subsection does not restrict the authority of a State or political subdivision of a State to continue to enforce any ~~State~~ statute enacted, or administrative action taken, prior to the date on which the Administrator defines **and publishes** the scope of a safety assessment and safety determination under section 6(a)(2).

"(B) LIMITATION.—Subparagraph (A) does not allow a State or political subdivision of a State to enforce any new prohibition or restriction under a ~~State~~ statute or administrative action described in that subparagraph, if the prohibition or restriction is established after the date described in that subparagraph.

"(c) Scope of Preemption.—Federal preemption under subsections (a) and (b) of ~~State~~ statutes and administrative actions applicable to specific substances shall apply only to—

"(1) the chemical substances or category of substances subject to a rule, order, or consent agreement under section 4;

"(2) the **hazards, exposures, risks, and** uses or conditions of use of such substances that are identified by the Administrator as subject to review in a safety assessment and included in the scope of the safety determination made by the Administrator for the substance, or of any rule the Administrator promulgates pursuant to section 6(d); or

"(3) the uses of such substances that the Administrator has specified as significant new uses and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

"(d) Exceptions.—

"(1) NO PREEMPTION OF ~~STATE~~ STATUTES AND ADMINISTRATIVE ACTIONS.—

"(A) IN GENERAL.—Nothing in this Act, nor any amendment made by this Act, nor any rule, standard of performance, safety determination, or scientific assessment

implemented pursuant to this Act, shall affect the right of a State or a political subdivision of a State to adopt or enforce any rule, standard of performance, safety determination, scientific assessment, or any protection for public health or the environment that—

"(i) is adopted or authorized under the authority of any other Federal law or adopted to satisfy or obtain authorization or approval under any other Federal law;

"(ii) implements a reporting, monitoring, disclosure, or other information obligation for the chemical substance not otherwise required by the Administrator under this Act or required under any other Federal law;

"(iii) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal, except to the extent that the action—

"(I) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

"(II)(aa) addresses the same hazards and exposures, with respect to the same conditions of use as are included in the scope of the safety determination pursuant to section 6, but is inconsistent with the action of the Administrator; or

"(bb) would cause a violation of the applicable action by the Administrator under section 5 or 6; or

"(iv) subject to subparagraph (B), is identical to a requirement prescribed by the Administrator.

"(B) IDENTICAL REQUIREMENTS.—

"(i) IN GENERAL.—The penalties and other sanctions applicable under ~~State law~~ **a law of a State or political subdivision of a State** in the event of noncompliance with the identical requirement shall be no more stringent than the penalties and other sanctions available to the Administrator under section 16 of this Act.

"(ii) PENALTIES.—In the case of an identical ~~requirement, no State may~~ **requirement—**

"(I) a State or political subdivision of a State may not assess a penalty for a specific violation for which the Administrator has ~~already~~ assessed ~~a~~ **an adequate** penalty under section 16~~, and~~ **; and**

"(II) if a State or political subdivision of a State has assessed a penalty for a specific violation, the Administrator may not assess a penalty ~~under section 16 for a specific violation for which a State has already assessed a penalty.~~ **for that violation in an amount that would cause the total of the penalties assessed for the violation by the State or political subdivision of a State and the Administrator combined to exceed the maximum amount that may be assessed for that violation by the Administrator under section 16.**

"(2) APPLICABILITY TO CERTAIN RULES OR ORDERS.—Notwithstanding subsection (e)—

"(A) nothing in this section shall be construed as modifying the effect under this section, as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, of any rule or order promulgated or issued under this Act prior to that effective date; and

"(B) with respect to a chemical substance or mixture for which any rule or order was promulgated or issued under section 6 prior to the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act with regards to manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance, this section (as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act) shall govern the preemptive effect of any rule or order that is promulgated or issued respecting such chemical substance or mixture under section 6 of this Act after that effective date, unless the latter rule or order is with respect to a chemical substance or mixture containing a chemical substance and follows a designation of that chemical substance as a high-priority substance under **subsection (b) or (c) of** section 4A~~(b)~~ or as an additional priority for safety assessment and safety determination under section 4A(c).

Commented [A33]: These change are incorrect. The reference should be just to 4A(b), which is the provision under which high priority chemicals are designated; 4A(c) (industry priorities) is addressed at the end of the sentence.

"(e) Preservation of Certain ~~State Law.—~~ **Laws.—**

"(1) IN GENERAL.—Nothing in this Act, subject to subsection (g) of this section, shall—

"(A) be construed to preempt or otherwise affect the authority of a State or political subdivision of a State to continue to enforce any action taken before August 1, 2015, under the authority of a ~~State law~~ **law of the State or political subdivision of the State** that prohibits or otherwise restricts manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance; or

"(B) be construed to preempt or otherwise affect any action taken pursuant to a State law that was in effect on August 31, 2003.

Commented [A34]: Should be "law of a State or political subdivision of a State", consistent with changes made over time in other section 18 provisions.

"(2) EFFECT OF SUBSECTION.—This subsection does not affect, modify, or alter the relationship between ~~State and Federal law~~ **Federal law and laws of a State or political subdivision of a State** pursuant to any other Federal law.

"(f) ~~State~~ Waivers.—

"(1) DISCRETIONARY EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator may by rule, exempt from subsection (a), under such conditions as may be prescribed in the rule, a statute or administrative action of that State or political subdivision of the State that relates to the effects of, or exposure to, a chemical substance under the conditions of use if the Administrator determines that—

"(A) compelling ~~State or local~~ conditions warrant granting the waiver to protect health or the environment;

"(B) compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

"(C) compliance with the proposed requirement of the State or political subdivision

of the State would not cause a violation of any applicable Federal law, rule, or order; and

"(D) ~~based on~~ **in** the judgment of the Administrator, the proposed requirement of the State or political subdivision of the State is ~~consistent with sound objective scientific practices, the weight of the evidence, and~~ **designed to address a risk of a chemical substance, under the conditions of use, that was identified—**

"(i) consistent with the best available science;

"(ii) using supporting studies conducted in accordance with sound and objective scientific practices; and

"(iii) based on the weight of the scientific evidence.

"(2) REQUIRED EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—

"(A) compliance with the proposed requirement of the State ~~will~~ **or political subdivision of the State would** not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

"(B) compliance with the proposed requirement **of the State or political subdivision of the State** would not cause a violation of any applicable Federal law, rule, or order; and

"(C) the State or political subdivision of ~~a~~ **the** State has a concern about the chemical substance or use of the chemical substance based in peer-reviewed science.

"(3) DETERMINATION OF A ~~STATE~~ WAIVER REQUEST.—The duty of the Administrator to grant or deny a waiver application shall be nondelegable and shall be exercised—

"(A) not later than 180 days after the date on which an application under paragraph (1) is submitted; and

"(B) not later than ~~90~~ **110** days after the date on which an application under paragraph (2) is submitted.

"(4) FAILURE TO MAKE DETERMINATION.—If the Administrator fails to make a determination under paragraph (3)(B) during the ~~90~~ **110**-day period beginning on the date on which an application under paragraph (2) is submitted, the ~~State~~ statute or administrative action **of the State or political subdivision of the State** that was the subject of the application shall not be considered to be an existing statute or administrative action for purposes of subsection (b) by reason of the failure of the Administrator to make a determination.

Commented [A35]: This provision does not seem to have any effect and is confusing, but probably harmless.

"(5) NOTICE AND COMMENT.—Except in the case of an application approved under paragraph (9), the application of a State or political subdivision of ~~the~~ **a** State shall be subject to public notice and comment.

"(6) FINAL AGENCY ACTION.—The decision of the Administrator on the application of a State or political subdivision of ~~the~~ **a** State shall be—

"(A) considered to be a final agency action; and

"(B) subject to judicial review.

"(7) DURATION OF **WAIVERS.—A** ~~waivers.—~~

~~"(A) In general.—Except as provided in subparagraph (B), a~~ waiver granted under paragraph (2) or approved under paragraph (9) shall remain in **effect** ~~effect—~~

~~"(i)~~ until such time as the ~~safety assessment and safety determination is completed; or~~ **Administrator publishes the safety determination under section 6(a)(4).**

~~"(ii) subject to subparagraph (B), until judicial review of the failure of the Administrator to make a determination under paragraph (3) is sought under paragraph (8).~~

~~"(B) Reinstatement of waiver.—A waiver described in subparagraph (A)(ii) shall again take effect upon the earlier of—~~

~~"(i) the date of approval by the Administrator of the waiver application;~~

~~"(ii) the effective date of a court order directing the Administrator to approve the waiver application; or~~

~~"(iii) 90~~**"(8) JUDICIAL REVIEW OF WAIVERS.—Not later than 60** days after the date on which ~~judicial review under paragraph (8) is sought.~~

~~"(8) Judicial review of waivers.—Not later than 60 days after the date on which~~ the Administrator makes a determination on an application of a State or political subdivision of ~~the~~ **a** State under paragraph (1) or (2), ~~or not later than 60 days after the date on which the Administrator fails to make a determination under paragraph (3),~~ any person may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit, which shall have exclusive jurisdiction over the determination.

"(9) APPROVAL.—

"(A) ~~IN GENERAL.—IF~~ **AUTOMATIC APPROVAL.—If** the Administrator fails to meet the deadline ~~under section 6(a)(4) (including an extension granted under section 6(a)(6)), or the deadline~~ established under paragraph (3)(B), the application of a State or political subdivision of a State under paragraph (2) shall be automatically approved**, effective on the date that is 10 days after the deadline**.

"(B) REQUIREMENTS.—Notwithstanding paragraph (6), approval of a waiver application under subparagraph (A) for failure to meet the ~~deadlines under section 6(a)(4) (including an extension granted under section 6(a)(6))~~ **deadline under paragraph (3)(B)** shall not be considered final agency action or be subject to judicial review or public notice and comment.

~~"(10) Judicial review of low-priority decisions.—~~

~~"(A) In general.—Not later than 60 days after the publication of a designation under section 4A(b)(4), any person may commence a civil action to challenge the designation.~~

~~* 5 "(B) Jurisdiction.—The United States Court of Appeals for the District of Columbia~~

~~Circuit shall have exclusive jurisdiction over a civil action filed under this paragraph.~~

"(g) Savings.—

"(1) NO PREEMPTION OF COMMON LAW OR STATUTORY CAUSES OF ACTION FOR CIVIL RELIEF OR CRIMINAL CONDUCT.—

"(A) IN GENERAL.—Nothing in this Act, nor any amendment made by this Act, nor any safety standard, rule, requirement, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall be construed to preempt, displace, or supplant any state or Federal common law rights or any state or Federal statute creating a remedy for civil relief, including those for civil damage, or a penalty for a criminal conduct.

"(B) CLARIFICATION OF NO PREEMPTION.—Notwithstanding any other provision of this Act, nothing in this Act, nor any amendments made by this Act, shall preempt or preclude any cause of action for personal injury, wrongful death, property damage, or other injury based on negligence, strict liability, products liability, failure to warn, or any other legal theory of liability under any State law, maritime law, or Federal common law or statutory theory.

"(2) NO EFFECT ON PRIVATE REMEDIES.—

"(A) IN GENERAL.—Nothing in this Act, nor any amendments made by this Act, nor any rules, regulations, requirements, safety assessments, safety determinations, scientific assessments, or orders issued pursuant to this Act shall be interpreted as, in either the plaintiff's or defendant's favor, dispositive in any civil action.

"(B) AUTHORITY OF COURTS.—This Act does not affect the authority of any court to make a determination in an adjudicatory proceeding under applicable State or Federal law with respect to the admission into evidence or any other use of this Act or rules, regulations, requirements, standards of performance, safety assessments, scientific assessments, or orders issued pursuant to this Act.".

SEC. 18. JUDICIAL REVIEW.

Section 19 of the Toxic Substances Control Act (15 U.S.C. 2618) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph ~~(A),~~**(A)**—

(I) in the first sentence—

(aa) by striking "Not" and inserting "Except as otherwise provided in this title, not";

(bb) by striking "section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8, or under title II or IV" and inserting ~~"section 4(a), 5(d), 6(c), 6(d), 6(g), or 8, or title II or IV", and~~**"this title or title II or IV, or an order under section 6(c)(1)(A)"; and**

~~(ii) in subparagraph (B),~~**(cc) by striking "judicial review of such**

rule" and inserting "judicial review of such rule or order"; and

(II) in the second sentence, by striking "such a rule" and inserting "such a rule or order"; and

(ii) in subparagraph (B)—

(I) by striking "Courts" and inserting "Except as otherwise provided in this title, courts"; and

(II) by striking "an order issued under subparagraph (A) or (B) of section 6(b)(1)" and inserting "an order issued under this title"; ~~and~~

Commented [A36]: Should technically be an order other than a 6(c)(1)(A) order, since those are handled in (bb), above.

~~* 6 (B) in paragraph (2), in the first sentence, by striking "paragraph (1)(A)" and inserting "paragraph (1)"; and~~

(B) in paragraph (2), in the second sentence, by striking "the filing of the rulemaking record of proceedings on which the Administrator based the rule being reviewed" and inserting "the filing of the record of proceedings on which the Administrator based the rule or order being reviewed"; and

(C) by striking paragraph (3) ~~; and~~ **and inserting the following:**

"(3) JUDICIAL REVIEW OF LOW-PRIORITY DECISIONS.—

"(A) IN GENERAL.—Not later than 60 days after the publication of a designation under section 4A(b)(4), or a designation under section 4A(b)(8) of a chemical substance as a low-priority substance, any person may commence a civil action to challenge the designation.

** **5** "(B) JURISDICTION.—The United States Court of Appeals for the District of Columbia Circuit shall have exclusive jurisdiction over a civil action filed under this ~~paragraph.~~ **paragraph."; and**

(2) in subsection (c)(1)(B)—

(A) in clause (i)—

(i) by striking "section 4(a), 5(b)(4), 6(a), or 6(e)" and inserting "section 4(a), ~~5(d), 6(d), or 6(g)";~~ **6(d), or 6(g), or an order under section 6(c)(1)(A)";** and

Commented [A37]: This needs to be changed to 6(h), since the numbering of the PCB provision has changed.

Commented [A38]: There are several places in 19(c) where conforming changes should be made to add "order", where only "rule" is currently referenced.

(ii) by striking "evidence in the rulemaking record (as defined in subsection (a)(3)) taken as a whole;" and inserting "evidence (including any matter) in the rulemaking record, taken as a whole; and"; and

(B) by striking clauses (ii) and (iii) and the matter following clause (iii) and inserting the following:

"(ii) the court may not review the contents and adequacy of any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incorporated in the rule, except as part of the rulemaking record, taken as a whole.".

SEC. 19. CITIZENS' CIVIL ACTIONS.

Section 20 of the Toxic Substances Control Act (15 U.S.C. 2619) is amended—

(1) in subsection (a)(1), by striking "or order issued under section 5" and inserting "or order issued under section 4 or 5"; and

(2) in subsection (b)—

(A) in paragraph (1)(B), by striking "or" at the end;

(B) in paragraph (2), by striking the period at the end and inserting ", except that no prior notification shall be required in the case of a civil action brought to compel a decision by the Administrator pursuant to section 18(f)(3)(B); or"; and

(C) by adding at the end the following:

"(3) in the case of a civil action brought to compel a decision by the Administrator pursuant to section 18(f)(3)(B), after the date that is 60 days after the deadline specified in section 18(f)(3)(B).".

SEC. 20. CITIZENS' PETITIONS.

Section 21 of the Toxic Substances Control Act (15 U.S.C. 2620) is amended—

(1) in subsection (a), by striking "an order under section 5(e) or 6(b)(2)" and inserting "an order under section 4 or 5(d)"; and

(2) in subsection (b)—

(A) in paragraph (1), by striking "an order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)" and inserting "an order under section 4 or 5(d)"; and

(B) in paragraph (4), by striking subparagraph (B) and inserting the following:

"(B) DE NOVO PROCEEDING.—

"(i) IN GENERAL.—In an action under subparagraph (A) to initiate a proceeding to ~~promulgate~~ **issue** a rule pursuant to section 4, 5, 6, or 8 or issue an order under section 4 or 5(d), the petitioner shall be provided an opportunity to have the petition considered by the court in a de novo proceeding.

Commented [A39]: This is incorrect. There is no petition under the bill for section 5 rules.

"(ii) DEMONSTRATION.—

"(I) IN GENERAL.—The court in a de novo proceeding under this subparagraph shall order the Administrator to initiate the action requested by the petitioner if the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—

"(aa) in the case of a petition to initiate a proceeding for the issuance of a rule or order under section 4, the information ~~available to the Administrator is insufficient for the Administrator to perform an action described in section 4, 4A, 5, or 6(d);~~ **is needed for a purpose identified in section 4(a);**

"(bb) in the case of a petition to issue an order under section 5(d), ~~there is a reasonable basis to conclude that~~ the chemical substance is not likely to meet the safety standard;

"(cc) in the case of a petition to initiate a proceeding for the issuance of a rule under section 6(d), ~~there is a reasonable basis to conclude that~~ the chemical substance ~~will~~ **does** not meet the safety standard; or

"(dd) in the case of a petition to initiate a proceeding for the issuance of a rule under section 8, there is a reasonable basis to conclude that the rule is necessary to protect health or the environment or ensure that the chemical substance meets the safety standard.

"(II) DEFERMENT.—The court in a de novo proceeding under this subparagraph may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes, if the court finds that—

"(aa) the extent of the risk to health or the environment alleged by the petitioner is less than the extent of risks to health or the environment with respect to which the Administrator is taking action under this Act; and

"(bb) there are insufficient resources available to the Administrator to take the action requested by the petitioner.".

Commented [A40]: 1.There is no judicial review standard for petitions to issue or amend PCB rules under 6(h); 2. Per previous comments, this authority to force EPA to issue section 6(d) rules could force EPA action on chemicals that are lower priority than other chemicals EPA has not gotten to, and it could potentially significantly swell the ranks of chemicals simultaneously subject to 6(d) rulemaking.

SEC. ~~20~~ **21**. EMPLOYMENT EFFECTS.

Section 24(b)(2)(B)(ii) of the Toxic Substances Control Act (15 U.S.C. 2623(b)(2)(B)(ii)) is amended by striking "section 6(c)(3)," and inserting "the applicable requirements of this Act;".

SEC. ~~21.~~ **22.** STUDIES.

Section 25 of the Toxic Substances Control Act (15 U.S.C. 2624) is repealed.

SEC. ~~22.~~ **23.** ADMINISTRATION.

Section 26 of the Toxic Substances Control Act (15 U.S.C. 2625) is amended—

(1) by striking subsection (b) and inserting the following:

"(b) Fees.—

"(1) IN GENERAL.—The Administrator shall establish, not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, by rule—

"(A) the payment of 1 or more reasonable fees as a condition of submitting a notice or requesting an exemption under section 5; **and**

"(B) the payment of 1 or more reasonable fees by a manufacturer or processor that—

"(i) is required to submit a notice pursuant to the rule promulgated under section 8(b)(4)(A)(i) identifying a chemical substance as active;

"(ii) is required to submit a notice pursuant to section 8(b)(5)(B)(i) changing the status of a chemical substance from inactive to active;

"(iii) is required to report information pursuant to the rules promulgated under

paragraph (1) or (4) of section 8(a)~~(4); and~~**; or**

"(iv) manufactures or processes a chemical substance subject to a safety assessment and safety determination pursuant to section 6.

"(2) UTILIZATION AND COLLECTION OF FEES.—The Administrator shall—

"(A) utilize the fees collected under paragraph (1) only to defray costs associated with the actions of the Administrator—

"(i) to collect, process, review, provide access to, and protect from disclosure (where appropriate) information on chemical substances under this Act;

"(ii) to review notices and make determinations for chemical substances under paragraphs (1) and (3) of section 5(d) and impose any necessary restrictions under section 5(d)(4);

"(iii) to make prioritization decisions under section 4A;

"(iv) to conduct and complete safety assessments and determinations under section 6; and

"(v) to conduct any necessary rulemaking pursuant to section 6(d);

"(B) insofar as possible, collect the fees described in paragraph (1) in advance of conducting any fee-supported activity;

"(C) deposit the fees in the Fund established by paragraph (4)(A); and

"(D) **insofar as possible,** not collect excess fees or retain a significant amount of unused fees.

"(3) AMOUNT AND ADJUSTMENT OF FEES; REFUNDS.—In setting fees under this section, the Administrator shall—

"(A) ~~take into account the cost to the Administrator of conducting the activities described in paragraph (2);~~

~~"(B)~~ prescribe lower fees for small business concerns, after consultation with the Administrator of the Small Business Administration;

~~"(C)~~**"(B)** set the fees established under paragraph (1) at levels such that the fees will, in aggregate, provide a sustainable source of funds to ~~defray approximately~~ **annually defray—**

"(i) the lower of—

"(I) 25 percent of the costs of conducting the activities identified in paragraph (2)(A), ~~not to exceed $18,000,000, not including fees under subparagraph (E) of this paragraph;~~ **other than the costs to conduct and complete safety assessments and determinations under section 6 for chemical substances identified pursuant to section 4A(c); or**

~~"(D)~~**"(II) $25,000,000 (subject to adjustment pursuant to subparagraph (F)); and**

"(ii) the full costs and the 50-percent portion of the costs of safety

Commented [A41]: As currently drafted, it could be argued that money collected from industry requested Additional Priority Chemicals (identified under 4A(c)) counts against the fixed $25,000,000 cap. Unless that was the intention, it should be made clearer that such fees do not count against the fixed $25,000,000 cap.

Note that the language above in (b)(3)(B)(i)(I) does not address this issue.

It addresses a different issue, which is whether EPA should consider the costs of working on Additional Priority Chemicals when calculating the "25 percent of the costs" cap.

assessments and safety determinations specified in subparagraph (D);

"(C) reflect an appropriate balance in the assessment of fees between manufacturers and processors, and allow the payment of fees by consortia of manufacturers or processors;

"(D) notwithstanding subparagraph (B) and paragraph (4)(D)—

"(i)~~"(E)~~ for substances designated ~~as additional priorities~~ pursuant to section 4A(c)**(1)**, establish the fee at a level sufficient to defray the full **annual** costs to the Administrator of conducting the safety assessment and safety determination under section 6~~, except that~~**; and**

"(ii) for substances ~~subject~~ **designated pursuant** to section 4A(c)(3), ~~the Administrator shall~~ establish the fee at a level sufficient to defray 50 percent of ~~those costs;~~ **the annual costs to the Administrator of conducting the safety assessment and safety determination under section 6;**

~~"(F)~~**"(E)** prior to the establishment or amendment of any fees under paragraph (1), consult and meet with parties potentially subject to the fees or their representatives, subject to the condition that no obligation under the Federal Advisory Committee Act (5 U.S.C. App.) or subchapter III of chapter 5 of title 5, United States Code, is applicable with respect to such meetings;

~~"(G)~~**"(F)** beginning with the fiscal year that is 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and every 3 years thereafter, after consultation with parties potentially subject to the fees and their representatives **pursuant to subparagraph (E)**, increase or decrease the fees established under paragraph (1) as **necessary to adjust for inflation and to ensure, based on the audit analysis required under paragraph (5)(B),** ~~necessary—~~

~~"(i) to ensure~~ that funds deposited in the Fund are sufficient to **defray—**

"(i) approximately but not more than 25 percent of the annual costs to conduct the activities identified in paragraph (2)(A) ~~and the full~~ **, other than the costs to conduct and complete safety assessments and determinations under section 6 for chemical substances identified pursuant to section 4A(c); and**

"(ii) the full annual costs and the 50-percent portion of the **annual** costs of safety assessments and safety determinations ~~pursuant to~~ **specified in** subparagraph ~~(E), and~~**(D);**

~~"(ii) to account for inflation;~~

~~"(H)~~**"(G)** adjust fees established under paragraph (1) as necessary to vary on account of differing circumstances, including reduced fees or waivers in appropriate circumstances, to reduce the burden on manufacturing or processing, remove barriers to innovation, or where the costs to the Administrator of collecting the fees exceed the fee revenue anticipated to be collected; and

~~"(I)~~**"(H)** if a notice submitted under section 5 is refused or subsequently withdrawn, refund the fee or a portion of the fee if no substantial work was performed on the notice.

"(4) TSCA IMPLEMENTATION FUND.—

"(A) ESTABLISHMENT.—There is established in the Treasury of the United States a fund, to be known as the 'TSCA Implementation Fund' (referred to in this subsection as the 'Fund'), consisting of—

"(i) such amounts as are deposited in the Fund under paragraph (2)(C); and

"(ii) any interest earned on the investment of amounts in the Fund; and

"(iii) any proceeds from the sale or redemption of investments held in the Fund.

"(B) CREDITING AND AVAILABILITY OF FEES.—

"(i) IN GENERAL.—Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, and shall be available without fiscal year limitation.

"(ii) REQUIREMENTS.—Fees collected under this section shall not—

"(I) be made available or obligated for any purpose other than to defray the costs of conducting the activities identified in paragraph (2)(A);

"(II) otherwise be available for any purpose other than implementation of this Act; and

"(III) so long as amounts in the Fund remain available, be subject to restrictions on expenditures applicable to the Federal government as a whole.

"(C) UNUSED FUNDS.—Amounts in the Fund not currently needed to carry out this subsection shall be—

"(i) maintained readily available or on deposit;

"(ii) invested in obligations of the United States or guaranteed by the United States; or

"(iii) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

"(D) MINIMUM AMOUNT OF APPROPRIATIONS.—Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for ~~salaries, contracts, and expenses for the functions (as in existence in fiscal year 2015) of the Office of Pollution Prevention and Toxics~~ **the Chemical Risk Review and Reduction program project** of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for ~~covered functions for fiscal year 2015 (excluding the amount of any fees appropriated for the fiscal year).~~ **that program project for fiscal year 2014.**

"(5) AUDITING.—

"(A) FINANCIAL STATEMENTS OF AGENCIES.—For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of an executive agency.

"(B) COMPONENTS.—The annual audit required under sections 3515(b) and 3521 of

that title of the financial statements of activities under this subsection shall include an analysis of—

"(i) the fees collected under paragraph (1) and disbursed;

"(ii) compliance with the deadlines established in section 6 of this Act;

"(iii) the amounts budgeted, appropriated, collected from fees, and disbursed to meet the requirements of sections 4, 4A, 5, 6, 8, and 14, including the allocation of full time equivalent employees to each such section or activity; and

"(iv) the reasonableness of the allocation of the overhead associated with the conduct of the activities described in paragraph (2)(A).

"(C) INSPECTOR GENERAL.—The Inspector General of the Environmental Protection Agency shall—

"(i) conduct the annual audit required under this subsection; and

"(ii) report the findings and recommendations of the audit to the Administrator and to the appropriate committees of Congress.

"(6) TERMINATION.—The authority provided by this section shall terminate at the conclusion of the fiscal year that is 10 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, unless otherwise reauthorized or modified by Congress.";

(2) in subsection (e), by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services"; and

(3) adding at the end the following:

"(h) Prior Actions.—Nothing in this Act eliminates, modifies, or withdraws any rule promulgated, order issued, or exemption established pursuant to this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

SEC. ~~23~~ **24**. DEVELOPMENT AND EVALUATION OF TEST METHODS AND SUSTAINABLE CHEMISTRY.

~~Section~~**(a) In General.—Section** 27 of the Toxic Substances Control Act (15 U.S.C. 2626) is amended—

(1) in subsection (a), in the first sentence by striking "Health, Education, and Welfare" and inserting "Health and Human Services"; and

(2) by adding at the end the following:

"(c) ~~Sustainable Chemistry Program.—The President shall establish~~ **National Coordinating Entity for Sustainable Chemistry.—**

"(1) ESTABLISHMENT.—Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Director of the Office of Science and Technology Policy shall convene an entity under the National Science and Technology Council with the responsibility to coordinate Federal programs and activities in support of sustainable chemistry, including, as appropriate,

at the National Science Foundation, the Department of Energy, the Department of Agriculture, the Environmental Protection Agency, the National Institute of Standards and Technology, the Department of Defense, the National Institutes of Health, and other related Federal agencies.

"(2) CHAIRMAN.—The entity described in paragraph (1) shall be chaired by the Director of the National Science Foundation and the Assistant Administrator for the Office of Research and Development of the Environmental Protection Agency, or their designees.

"(3) DUTIES.—

"(A) IN GENERAL.—The entity described in paragraph (1) shall—

"(i) develop a working definition of sustainable chemistry, after seeking advice and input from stakeholders as described in clause (v);

"(ii) oversee the planning, management, and coordination of the Sustainable Chemistry Initiative described in subsection (d);

"(iii) develop a national strategy for sustainable chemistry as described in subsection (f);

"(iv) develop an implementation plan for sustainable chemistry as described in subsection (g); and

"(v) consult and coordinate with stakeholders qualified to provide advice and information on the development of the initiative, national strategy, and implementation plan for sustainable chemistry, at least once per year, to carry out activities that may include workshops, requests for information, and other efforts as necessary.

"(B) STAKEHOLDERS.—The stakeholders described in subparagraph (A)(v) shall include representatives from—

"(i) industry (including small- and medium-sized enterprises from across the value chain);

"(ii) the scientific community (including the National Academy of Sciences, scientific professional societies, and academia);

"(iii) the defense community;

"(iv) State, tribal, and local governments;

"(v) State or regional sustainable chemistry programs;

"(vi) nongovernmental organizations; and

"(vii) other appropriate organizations.

"(4) SUNSET.—

"(A) IN GENERAL.—On completion of the national strategy and accompanying implementation plan for sustainable chemistry as described in paragraph (3), the Director of the Office of Science and Technology Policy—

"(i) shall review the need for further work; and

"(ii) may disband the entity described in paragraph (1) if no further efforts are determined to be necessary.

"(B) NOTICE AND JUSTIFICATION.—The Director of the Office of Science and Technology Policy shall provide notice and justification, including an analysis of options to establish the Sustainable Chemistry Initiative described in subsection (d) and the partnerships described in subsection (e) within 1 or more appropriate Federal agencies, regarding a decision to disband the entity not less than 90 days prior to the termination date to the Committee on Science, Space, and Technology and the Committee on Energy and Commerce of the House of Representatives and the Committee on Environment and Public Works and the Committee on Commerce, Science, and Transportation of the Senate.

"(d) Sustainable Chemistry Initiative.—The entity described in subsection (c)(1) shall oversee the establishment of an interagency Sustainable Chemistry ~~Program~~ **Initiative** to promote and coordinate ~~Federal sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training activities.~~ **activities designed—**

~~"(d) Program Activities.—The activities of the Program shall be designed to—~~

~~"(1)~~ **"(1) to** provide sustained support for sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training through—

"(A) coordination **and promotion** of sustainable chemistry research, development, demonstration, and technology transfer conducted at Federal **and national** laboratories and ~~agencies; and~~

Federal agencies and at public and private institutions of higher education; and

"(B) to the extent practicable, encouragement of consideration of sustainable chemistry in, as appropriate—

"(i) the conduct of Federal ~~and~~**,** State**, and private** science and engineering research and development; and

"(ii) the solicitation and evaluation of applicable proposals for science and engineering research and development;

"(2) **to** examine methods by which the Federal Government can ~~create~~ **offer** incentives for consideration and use of sustainable chemistry processes and products~~, including~~ **that encourage competition and overcoming market barriers, including grants, loans, loan guarantees, and** innovative financing mechanisms;

"(3) **to** expand the education and training of undergraduate and graduate students and professional scientists and engineers, including through partnerships with industry **as described in subsection (e)**, in sustainable chemistry science and engineering;

"(4) **to** collect and disseminate information on sustainable chemistry research, development, and technology transfer**,** including information on—

"(A) incentives and impediments to development, manufacturing, and

Commented [A42]: This seems a little confusing. It looks like the Initiative and partnerships will have been established by this point already. What is the contemplated additional step of establishing them within an agency? And how can a partnership be within an agency?

Commented [A43]: (c)(3) indicates that the entity will oversee the planning, management and coordination of the Initiative. Seems best to use the same terms to describe functions.

commercialization;

"(B) accomplishments;

"(C) best practices; and

"(D) costs and benefits; **and**

"(5) **to** support (including through technical assistance, participation, financial support, or other forms of support) economic, legal, and other appropriate social science research to identify barriers to commercialization and methods to advance commercialization of sustainable chemistry.

"(e) ~~Interagency Working Group.—~~ **Partnerships in Sustainable Chemistry.—**

~~"(1) Establishment.—Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the President, in consultation with the Office of Science and Technology Policy, shall establish an Interagency Working Group that shall include representatives from the National Science Foundation, the National Institute of Standards and Technology, the Department of Energy, the Environmental Protection Agency, the Department of Agriculture, the Department of Defense, the National Institutes of Health, and any other agency that the President may designate to oversee the planning, management, and coordination of the Program.~~

~~"(2) Governance.—The Director of the National Science Foundation and the Assistant Administrator for Research and Development of the Environmental Protection Agency, or their designees, shall serve as co-chairs of the Interagency Working Group.~~

~~"(3) Responsibilities.—In overseeing the planning, management, and coordination of the Program, the Interagency Working Group shall—~~

~~"(A) establish goals and priorities for the Program, in consultation with the Advisory Council;~~

~~"(B) provide for interagency coordination, including budget coordination, of activities under the Program;~~

~~"(C) meet not later than 90 days from its establishment and periodically thereafter; and~~

~~"(D) establish and consult with an Advisory Council on a regular basis.~~

~~"(4) Membership.—The Advisory Council members shall not be employees of the Federal Government and shall include a diverse representation of knowledgeable individuals from the private sector (~~**"(1) IN GENERAL.—The entity described in subsection (c)(1), itself or through an appropriate subgroup designated or established by the entity, shall work through the agencies described in subsection (c)(1) to support, through financial, technical, or other assistance, the establishment of partnerships between institutions of higher education, nongovernmental organizations, consortia, and companies across the value chain in the chemical industry,** including small- and medium-sized ~~enterprises from across the value chain), academia, State and tribal governments, and nongovernmental organizations and others who are in a position to provide expertise.~~

~~"(f) Agency Budget Requests.—~~

~~"(1) In general.—Each Federal agency and department participating in the Program shall, as part of its annual request for appropriations to the Office of Management and Budget, submit a report to the Office of Management and Budget that—~~

~~"(A) identifies the activities of the agency or department that contribute directly to the Program; and~~

~~"(B) states the portion of the agency or department's request for appropriations that is allocated to those activities.~~

~~"(2) Annual budget request to congress.—The President shall include in the annual budget request to Congress a statement of the portion of the annual budget request for each agency or department that will be allocated to activities undertaken pursuant to the Program.~~

~~"(g) Report~~ **enterprises—**

"(A) to establish collaborative research, development, demonstration, technology transfer, and commercialization programs; and

"(B) to train students and retrain professional scientists and engineers in the use of sustainable chemistry concepts and strategies by methods including—

"(i) developing curricular materials and courses for undergraduate and graduate levels and for the professional development of scientists and engineers; and

"(ii) publicizing the availability of professional development courses in sustainable chemistry and recruiting scientists and engineers to pursue those courses.

"(2) PRIVATE SECTOR ENTITIES.—To be eligible for support under this section, a partnership in sustainable chemistry shall include at least 1 private sector entity.

"(3) SELECTION OF PARTNERSHIPS.—In selecting partnerships for support under this section, the entity and the agencies described in subsection (c)(1) shall also consider the extent to which the applicants are willing and able to demonstrate evidence of support for, and commitment—

"(A) to achieving the goals of the Sustainable Chemistry Initiative described in subsection (d); and

"(B) to sustaining any new innovations, tools, and resources generated from funding under the program.

"(4) PROHIBITED USE OF FUNDS.—Financial support provided under this section may not be used—

"(A) to support or expand a regulatory chemical management program at an implementing agency under a State law; or

"(B) to construct or renovate a building or structure.

"(f) National Strategy to Congress.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the ~~Interagency Working Group~~

entity described in subsection (c)(1) shall submit ~~a report~~ to the Committee on Science, Space, and Technology and **the** Committee on Energy and Commerce of the House of Representatives and the Committee on Environment and Public Works and the Committee on Commerce, Science, and Transportation of the Senate**, a national strategy** that shall include—

"(A) a summary of federally funded sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training activities;

"(B) a summary of the financial resources allocated to sustainable chemistry initiatives;

"(C) an analysis of the progress made toward achieving the goals and priorities of the ~~program established pursuant to~~ **Sustainable Chemistry Initiative described in** subsection ~~(c)~~**(d)**, and recommendations for future ~~program activities;~~ **initiative activities, including consideration of options to establish the Sustainable Chemistry Initiative and the partnerships described in subsection (e) within 1 or more appropriate Federal agencies;**

Commented [A44]: Same comment as above re meaning of this language.

"(D) an assessment of the benefits of expanding existing, federally -supported regional innovation and manufacturing hubs to include sustainable chemistry and the value of directing the ~~creation~~ **establishment** of 1 or more dedicated sustainable chemistry centers of excellence or hubs; ~~and~~

"(E) an evaluation of steps taken and future strategies to avoid duplication of efforts, streamline interagency coordination, facilitate information sharing, and spread best practices between participating agencies in the ~~Program.~~

Sustainable Chemistry Initiative; and

"(F) a framework for advancing sustainable chemistry research, development, technology transfer, commercialization, and education and training.

"(2) SUBMISSION TO GAO.—The ~~Interagency Working Group shall also submit the report~~ **entity described in subsection (c)(1) shall submit the national strategy** described in paragraph (1) to the Government Accountability Office for consideration in future Congressional ~~inquiries.".~~ **inquiries.**

~~SEC. 24~~**"(g) Implementation Plan.—Not later than 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the entity described in subsection (c)(1) shall submit to the Committee on Science, Space, and Technology and the Committee on Energy and Commerce of the House of Representatives and the Committee on Environment and Public Works and the Committee on Commerce, Science, and Transportation of the Senate, an implementation plan, based on the findings of the national strategy and other assessments, as appropriate, for sustainable chemistry.".**

(b) Sustainable Chemistry Basic Research.—Subject to the availability of appropriated funds, the Director of the National Science Foundation shall continue to carry out the Green Chemistry Basic Research program authorized under section 509 of the National Science Foundation Authorization Act of 2010 (42 U.S.C. 1862p–3).

SEC. 25. STATE PROGRAMS.

Section 28 of the Toxic Substances Control Act (15 U.S.C. 2627) is amended—

(1) in subsection (b)(1)—

(A) in subparagraphs (A) through (D), by striking the comma at the end of each subparagraph and inserting a semicolon; and

(B) in subparagraph (E), by striking ", and" and inserting "; and"; and

(2) by striking subsections (c) and (d).

SEC. ~~25~~ 26. AUTHORIZATION OF APPROPRIATIONS.

Section 29 of the Toxic Substances Control Act (15 U.S.C. 2628) is repealed.

SEC. ~~26~~ 27. ANNUAL REPORT.

Section 30 of the Toxic Substances Control Act (15 U.S.C. 2629) is amended by striking paragraph (2) and inserting the following:

"(2)(A) the number of notices received during each year under section 5; and

"(B) the number of the notices described in subparagraph (A) for chemical substances subject to a rule, testing consent agreement, or order under section 4;".

SEC. ~~27~~ 28. EFFECTIVE DATE.

Section 31 of the Toxic Substances Control Act (15 U.S.C. 2601 note; Public Law 94–469) is amended—

(1) by striking "Except as provided in section 4(f), this" and inserting the following:

"(a) In General.—This"; and

(2) by adding at the end the following:

"(b) Retroactive Applicability.—Nothing in this Act shall be interpreted to apply retroactively to any State, Federal, or maritime legal action commenced prior to the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

SEC. 29. ELEMENTAL MERCURY.

(a) Temporary Generator Accumulation.—Section 5 of the Mercury Export Ban Act of 2008 (42 U.S.C. 6939f) is amended—

(1) in subsection (a)(2), by striking "2013" and inserting "2019";

(2) in subsection (b)—

(A) in paragraph (1)—

(i) by redesignating subparagraphs (A), (B), and (C), as clauses (i), (ii), and (iii), respectively and indenting appropriately;

(ii) in the first sentence, by striking "After consultation" and inserting the following:

"(A) ASSESSMENT AND COLLECTION.—After consultation";

(iii) in the second sentence, by striking "The amount of such fees" and inserting the following:

"(B) AMOUNT.—The amount of the fees described in subparagraph (A)";

(iv) in subparagraph (B) (as so designated)—

(I) in clause (i) (as so redesignated), by striking "publically available not later than October 1, 2012" and inserting "publicly available not later than October 1, 2018";

(II) in clause (ii) (as so redesignated), by striking "and";

(III) in clause (iii) (as so redesignated), by striking the period at the end and inserting ", subject to clause (iv); and"; and

(IV) by adding at the end the following:

"(iv) for generators temporarily accumulating elemental mercury in a facility subject to subparagraphs (B) and (D)(iv) of subsection (g)(2) if the facility designated in subsection (a) is not operational by January 1, 2019, shall be adjusted to subtract the cost of the temporary accumulation during the period in which the facility designated under subsection (a) is not operational."; and

(v) by adding at the end the following:

"(C) CONVEYANCE OF TITLE AND PERMITTING.—If the facility designated in subsection (a) is not operational by January 1, 2020, the Secretary—

"(i) shall immediately accept the conveyance of title to all elemental mercury that has accumulated in facilities in accordance with subsection (g)(2)(D), before January 1, 2020, and deliver the accumulated mercury to the facility designated under subsection (a) on the date on which the facility becomes operational;

"(ii) shall pay any applicable Federal permitting costs, including the costs for permits issued under section 3005(c) of the Solid Waste Disposal Act (42 U.S.C. 6925(c)); and

"(iii) shall store, or pay the cost of storage of, until the time at which a facility designated in subsection (a) is operational, accumulated mercury to which the Secretary has title under this subparagraph in a facility that has been issued a permit under section 3005(c) of the Solid Waste Disposal Act (42 U.S.C. 6925(c))."; and

** **6** (B) in paragraph (2), in the first sentence, by striking "paragraph ~~(1)(A)~~**(1)(C)**" and inserting "paragraph ~~(1)~~**(1)(B)(iii)**"; and

(3) in subsection (g)(2)—

(A) in the undesignated material at the end, by striking "This subparagraph" and inserting the following:

Commented [A45]: This provision does not require DOE to accept conveyance of title to mercury that is being temporarily stored at RCRA-permitted facilities under existing MEBA authority. Also, because the applicability of this provision is limited to mercury waste generated/accumulated before 2020, it does not account for mercury waste generated after 2020, if the DOE facility is still not operational. It is also unclear what "conveyance of title" means, whether it is legal title only or possession as well.

Commented [A46]: It is unclear whose "federal permitting costs" this provision refers to. Under this provision, certain generators (as described herein) can accumulate on-site for more than 90 days without a RCRA permit, and under existing MEBA, RCRA permitted facilities can store temporarily. Is the intent to cover the costs for those permitted facilities?

"(C) Subparagraph (B)";

(B) in subparagraph (C) (as added by paragraph (1)), by inserting "of that subparagraph" before the period at the end; and

(C) by adding at the end the following:

"(D) A generator producing elemental mercury incidentally from the beneficiation or processing of ore or related pollution control activities, may accumulate the mercury produced onsite that is destined for a facility designated by the Secretary under subsection (a), for more than 90 days without a permit issued under section 3005(c) of the Solid Waste Disposal Act (42 U.S.C. 6925(c)), and shall not be subject to the storage prohibition of section 3004(j) of that Act (42 U.S.C. 6924(j)), if—

"(i) the Secretary is unable to accept the mercury at a facility designated by the Secretary under subsection (a) for reasons beyond the control of the generator;

"(ii) the generator certifies in writing to the Secretary that the generator will ship the mercury to a designated facility when the Secretary is able to accept the mercury;

"(iii) the generator certifies in writing to the Secretary that the generator is storing only mercury the generator has produced or recovered onsite and will not sell, or otherwise place into commerce, the mercury; and

"(iv) the generator has obtained an identification number under section 262.12 of title 40, Code of Federal Regulations, and complies with the requirements described in paragraphs (1) through (4) of section 262.34(a) of title 40, Code of Federal Regulations (as in effect on the date of enactment of this subparagraph).

"(E) MANAGEMENT STANDARDS FOR TEMPORARY STORAGE.—Not later than January 1, 2017, the Secretary, after consultation with the Administrator of the Environmental Protection Agency and State agencies in affected States, shall develop and make available guidance that establishes procedures and standards for the management and short-term storage of elemental mercury at a generator covered under subparagraph (D), including requirements to ensure appropriate use of flasks or other suitable containers. Such procedures and standards shall be protective of human health and the environment and shall ensure that the elemental mercury is stored in a safe, secure, and effective manner. A generator may accumulate mercury in accordance with subparagraph (D) immediately upon enactment of this Act, and notwithstanding that guidance called for by this paragraph (E) has not been developed or made available.".

(b) Interim Status.—Section 5(d)(1) of the Mercury Export Ban Act of 2008 (42 U.S.C. 6939f(d)(1)) is amended—

(1) in the fourth sentence, by striking "in existence on or before January 1, 2013,"; and

(2) in the last sentence, by striking "January 1, 2015" and inserting "January 1,

Commented [A47]: Currently under RCRA, the accumulation of waste for more than 90 days is considered "storage" and requires a RCRA permit. MEBA currently allows for temporary storage of elemental mercury destined for the DOE facility at RCRA-permitted treatment, storage or disposal facilities (that make certain certifications). This paragraph would allow certain generators of elemental mercury to effectively store without a permit.

Commented [A48]: Section 262.34(a)(1)-(4) is intended for generators accumulating on site for less than 90 days and does not provide the same level of protection against spills nor impose emergency response requirements typically required of a RCRA permitted facility.

Those regulations apply to generators that accumulate RCRA hazardous waste on-site for ***90 days or less***. Thus, this provision would allow for longer generator on-site accumulation time for mercury than what RCRA regulations currently allow (for generator on-site accumulation time for other RCRA hazardous waste), but without the additional requirements that apply to RCRA-permitted treatment, storage and disposal facilities, such as:

- Requirements related to emergency response or spill cleanup
- The permitting requirements of RCRA section 3005 (which would not apply here), which provide for facility-specific requirements in the permit for each treatment, storage and disposal (TSD) facility to ensure the facility is designed and operated to safely manage the hazardous wastes it handles, including any terms and conditions necessary to protect human health and the environment.
- RCRA section 3007(e) requires that EPA or the state conduct a thorough inspection of each TSD facility at least once every other year; there is no required inspection interval for generator facilities, which are inspected as resources allow.
- The regulations at 40 C.F.R. Part 264 (and Part 265) contain detailed requirements for operation and maintenance of TSD facilities (and interim status TSD facilities). Some key requirements that would not apply to generators accumulating mercury on-site under the amendment are:
  - Facility security, including preventing unauthorized entry;
  - Regular inspection of monitoring, safety, emergency, and security equipment, as well as operating and structural equipment; and

Commented [A49]: This allows DOE to issue nonbinding guidance for management of waste which otherwise would be subject to EPA's RCRA authority; currently under RCRA, a generator accumulating mercury wastes on-site for more than 90 days must obtain a RCRA permit. Under this provision, EPA only has a consultation role as DOE develops its nonbinding guidance. This paragraph also allows the generators described above to start accumulating now, even though no guidance is available; thus allowing generators to store mercury over 90 days with limited management requirements.

Commented [A50]: The provision being amended is intended to provide RCRA interim status to the designated DOE facility until a final decision on a RCRA permit is issued. EPA's preliminary read of the original provision is that it was ineffective because all states (except IA/AK) are authorized for the RCRA base program, which includes interim status.

So these amendments still may not have the desired effect.

2020".

(c) Mercury Inventory.—Section 8(b) of the Toxic Substances Control Act (15 U.S.C. 2607(b)) (as amended by section 10(2)) is amended by adding at the end the following:

"(10) MERCURY.—

"(A) DEFINITION OF MERCURY.—In this paragraph, notwithstanding section 3(2)(B), the term 'mercury' means—

"(i) elemental mercury; and

"(ii) a mercury compound.

"(B) PUBLICATION.—Not later than April 1, 2017, and every 3 years thereafter, the Administrator shall publish in the Federal Register an inventory of mercury supply, use, and trade in the United States.

"(C) PROCESS.—In carrying out the inventory under subparagraph (B), the Administrator shall—

"(i) identify any remaining manufacturing processes or products that intentionally add mercury; and

"(ii) recommend actions, including proposed revisions of Federal law (including regulations), to achieve further reductions in mercury use.

"(D) REPORTING.—

"(i) IN GENERAL.—To assist in the preparation of the inventory under subparagraph (B), any person who manufactures mercury or mercury-added products or otherwise intentionally uses mercury in a manufacturing process shall make periodic reports to the Administrator, at such time and including such information as the Administrator shall determine by rule promulgated not later than 2 years after the date of enactment of this paragraph.

"(ii) COORDINATION.—To avoid duplication, the Administrator shall coordinate the reporting under this subparagraph with the Interstate Mercury Education and Reduction Clearinghouse.

"(iii) EXEMPTION.—This subparagraph shall not apply to a person engaged in the generation, handling, or management of mercury-containing waste, unless that person manufactures or recovers mercury in the management of that waste.".

(d) Prohibition on Export of Certain Mercury Compounds.—Section 12(c) of the Toxic Substances Control Act (15 U.S.C. 2611(c)) (as amended by section 13(3)) is amended—

(1) in the subsection heading, by inserting "and Mercury Compounds" after "Mercury"; and

(2) by inserting after paragraph (2) the following:

"(3) PROHIBITION ON EXPORT OF CERTAIN MERCURY COMPOUNDS.—

"(A) IN GENERAL.—Effective January 1, 2020, the export of the following mercury compounds is prohibited:

Commented [A51]: It might make sense to change the title of section 8(b) from "Inventory" to "Inventories", since it will contain two completely unrelated inventories if this is added.

Commented [A52]: This seems unnecessary and has potential negative implications for EPA's interpretation of the MEBA provisions already codified in TSCA sections 6 and 12. EPA has interpreted those provisions as covering even mercury that does not qualify as a chemical substance under section 3(2)(B) of TSCA, and the inclusion of the notwithstanding clause here could call that interpretation into question. Also, the bill does not add a "notwithstanding" provision in the 12(c) amendments, below.

Commented [A53]: It is not clear what EPA is supposed to do here with respect to regulations. Is the intent that EPA recommend proposed regulations? Are we making that recommendation to ourselves? And does the bill give EPA additional rulemaking authority for this purpose?

Commented [A54]: EPA has interpreted the existing MEBA provisions codified in sections 6 and 12 as generally not covering mercury waste. There is some concern that the specific exemption here in 8(b) will call that general interpretation into question.

"(i) Mercury (I) chloride or calomel.

"(ii) Mercury (II) oxide.

"(iii) Mercury (II) sulfate.

"(iv) Mercury (II) nitrate.

"(v) Cinnabar or mercury sulphide.

"(vi) Any mercury compound that the Administrator, at the discretion of the Administrator, adds to the list by rule, on determining that exporting that mercury compound for the purpose of regenerating elemental mercury is technically feasible.

"(B) PUBLICATION.—Not later than 90 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and as appropriate thereafter, the Administrator shall publish in the Federal Register a list of the mercury compounds that are prohibited from export under this paragraph.

"(C) PETITION.—Any person may petition the Administrator to add to the list of mercury compounds prohibited from export.

"(D) ENVIRONMENTALLY SOUND DISPOSAL.—This paragraph does not prohibit the export of mercury (I) chloride or calomel for environmentally sound disposal to member countries of the Organization for Economic Cooperation and Development, on the condition that no mercury or mercury compounds are to be recovered, recycled, or reclaimed for use, or directly reused.

"(E) REPORT.—Not later than 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall evaluate any exports of calomel for disposal that occurred since that date of enactment and shall submit to Congress a report that contains the following:

"(i) volumes and sources of calomel exported for disposal;

"(ii) receiving countries of such exports;

"(iii) methods of disposal used;

"(iv) issues, if any, presented by the export of calomel;

"(v) evaluation of calomel management options in the United States, if any, that are commercially available and comparable in cost and efficacy to methods being utilized in the receiving countries; and

"(vi) a recommendation regarding whether Congress should further limit or prohibit the export of calomel for disposal.

"(F) EFFECT ON OTHER LAW.—Nothing in this paragraph shall be construed to affect the authority of the Administrator under Solid Waste Disposal Act (42 U.S.C. 6901 et seq.).".

SEC. 30. TREVOR'S LAW.

Commented [A55]:

1.By explicitly identifying calomel as eligible for export, there is an implication that all other compounds cannot be exported, even as waste. There is also an implication that elemental mercury cannot be exported as waste. This is inconsistent with EPA's interpretation of MEBA, and could also have implications for products and the federal transfer ban, and potentially use of mercury compounds in laboratories or research facilities.

2.The effect of this provision in operation would be to allow the export of these compounds for disposal only to Canada By allowing the export of mercury chloride and calomel to OECD member countries for disposal, the U.S. (a non-Party to the Basel Convention) would be sending hazardous waste to Basel parties. The Basel Convention prohibits the trade of hazardous waste between Basel Parties and non-Basel Parties, in the absence of an appropriate Article 11 agreement or arrangement under the Basel Convention. Although the U.S. is a member of the OECD, and the OECD agreement is considered an appropriate Basel Article 11 agreement, the OECD agreement is limited to exports for recovery and recyling only, and not disposal which is what this provision allows. Thus OECD member countries (except for Canada) would not be able to receive mercury wastes for disposal.

(a) Purposes.—The purposes of this section are—

(1) to provide the appropriate Federal agencies with the authority to help conduct investigations into potential cancer clusters;

(2) to ensure that Federal agencies have the authority to undertake actions to help address cancer clusters and factors that may contribute to the creation of potential cancer clusters; and

(3) to enable Federal agencies to coordinate with other Federal, State, and local agencies, institutes of higher education, and the public in investigating and addressing cancer clusters.

(b) Designation and Investigation of Potential Cancer Clusters.—Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

"SEC. 399V–6. DESIGNATION AND INVESTIGATION OF POTENTIAL CANCER CLUSTERS.

"(a) Definitions.—In this section:

"(1) CANCER CLUSTER.—The term 'cancer cluster' means the incidence of a particular cancer within a population group, a geographical area, or a period of time that is greater than expected for such group, area, or period.

"(2) PARTICULAR CANCER.—The term 'particular cancer' means one specific type of cancer or a type of cancers scientifically proven to have the same cause.

"(3) POPULATION GROUP.—The term 'population group' means a group, for purposes of calculating cancer rates, defined by factors such as race, ethnicity, age, or gender.

"(b) Criteria for Designation of Potential Cancer Clusters.—

"(1) DEVELOPMENT OF CRITERIA.—The Secretary shall develop criteria for the designation of potential cancer clusters.

"(2) REQUIREMENTS.—The criteria developed under paragraph (1) shall consider, as appropriate—

"(A) a standard for cancer cluster identification and reporting protocols used to determine when cancer incidence is greater than would be typically observed;

"(B) scientific screening standards that ensure that a cluster of a particular cancer involves the same type of cancer, or types of cancers;

"(C) the population in which the cluster of a particular cancer occurs by factors such as race, ethnicity, age, and gender, for purposes of calculating cancer rates;

"(D) the boundaries of a geographic area in which a cluster of a particular cancer occurs so as not to create or obscure a potential cluster by selection of a specific area; and

"(E) the time period over which the number of cases of a particular cancer, or

the calculation of an expected number of cases, occurs.

"(c) Guidelines for Investigation of Potential Cancer Clusters.—The Secretary, in consultation with the Council of State and Territorial Epidemiologists and representatives of State and local health departments, shall develop, publish, and periodically update guidelines for investigating potential cancer clusters. The guidelines shall—

"(1) require that investigations of cancer clusters—

"(A) use the criteria developed under subsection (b);

"(B) use the best available science; and

"(C) rely on a weight of the scientific evidence;

"(2) provide standardized methods of reviewing and categorizing data, including from health surveillance systems and reports of potential cancer clusters; and

"(3) provide guidance for using appropriate epidemiological and other approaches for investigations.

"(d) Investigation of Cancer Clusters.—

"(1) SECRETARY DISCRETION.—The Secretary—

"(A) in consultation with representatives of the relevant State and local health departments, shall consider whether it is appropriate to conduct an investigation of a potential cancer cluster; and

"(B) in conducting investigations shall have the discretion to prioritize certain potential cancer clusters, based on the availability of resources.

"(2) COORDINATION.—In investigating potential cancer clusters, the Secretary shall coordinate with agencies within the Department of Health and Human Services and other Federal agencies, such as the Environmental Protection Agency.

"(3) BIOMONITORING.—In investigating potential cancer clusters, the Secretary shall rely on all appropriate biomonitoring information collected under other Federal programs, such as the National Health and Nutrition Examination Survey. The Secretary may provide technical assistance for relevant biomonitoring studies of other Federal agencies.

"(e) Duties.—The Secretary shall—

"(1) ensure that appropriate staff of agencies within the Department of Health and Human Services are prepared to provide timely assistance, to the extent practicable, upon receiving a request to investigate a potential cancer cluster from a State or local health authority;

"(2) maintain staff expertise in epidemiology, toxicology, data analysis, environmental health and cancer surveillance, exposure assessment, pediatric health, pollution control, community outreach, health education, laboratory sampling and analysis, spatial mapping, and informatics;

"(3) consult with community members as investigations into potential cancer clusters are conducted, as the Secretary determines appropriate;

"(4) collect, store, and disseminate reports on investigations of potential cancer clusters, the possible causes of such clusters, and the actions taken to address such clusters; and

"(5) provide technical assistance for investigating cancer clusters to State and local health departments through existing programs, such as the Epi-Aids program of the Centers for Disease Control and Prevention and the Assessments of Chemical Exposures program of the Agency for Toxic Substances and Disease Registry.".

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 1/21/2016 12:14:44 AM
To: 'Deveny, Adrian (Merkley)' [Adrian_Deveny@merkley.senate.gov]
Subject: Administration Views Letter on TSCA Reform
Attachments: TSCA Reform Views.Boxer.pdf

Adrian,
Please see attached and let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/13/2015 3:34:14 PM
To: 'Abraham, Nick' [Nick.Abraham@mail.house.gov]
Subject: FW: Invitation to Testify 4/14/15
Attachments: EPA test.TSCA.4.14.15.docx

Nick,
Forwarding our testimony for the TSCA hearing on Tuesday, April 14, 2015, at 10:15 am per suggestion of committee staff. Also, I would like to request three seats for EPA please. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Kaiser, Sven-Erik
Sent: Monday, April 13, 2015 11:30 AM
To: 'Wilkerson, Jessica'; 'Couri, Jerry'
Subject: RE: Invitation to Testify 4/14/15

Jessica,
Attached please find Jim Jones's testimony for the hearing on Tuesday, April 14, 2015, at 10:15 p.m. before the Subcommittee on Environment and the Economy entitled, "H.R. ____, the TSCA Modernization Act of 2015." We will bring the completed truth in testimony form to the hearing. Please let me know if any questions.
Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Wilkerson, Jessica [mailto:Jessica.Wilkerson@mail.house.gov]
Sent: Thursday, April 09, 2015 3:51 PM
To: Kaiser, Sven-Erik
Subject: Invitation to Testify 4/14/15

Assistant Administrator Jones,

Attached is a courtesy copy of your invitation to testify on Tuesday, April 14, 2015, at 10:15 p.m., at the Subcommittee on Environment and the Economy hearing entitled, "H.R. ____, the TSCA Modernization Act of 2015." The formal invitation has been sent in the mail.

Please submit your testimony, truth in testimony, and CV forms electronically to me (jessica.wilkerson@mail.house.gov) by close of business Friday, April 10, 2015.

I have also attached instructions for submitting testimony, a truth in testimony form with instructions, and

the 114th Congress Committee rules. Please let me know if you have any questions or concerns.

Thank you,

Jessica Wilkerson | Legislative Clerk
U.S. House Committee on Energy and Commerce
(202) 225-2927

TESTIMONY OF
JAMES JONES
ASSISTANT ADMINISTRATOR
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
COMMITTEE ON ENERGY AND COMMERCE COMMITTEE
ENVIRONMENT AND THE ECONOMY SUBCOMMITTEE
UNITED STATES CONGRESS

April 14, 2015

Good morning Chairman Shimkus, Ranking Member Tonko, and other members of the Subcommittee. I appreciate the opportunity to join you today to discuss much needed reform of chemicals management in the United States and the opportunity to engage early on the recently released discussion draft of the "TSCA Modernization Act of 2015."

There continues to be wide agreement on the importance of ensuring chemical safety and restoring the public's confidence that the chemicals used in the products they and their families use are safe. This Administration also believes it is crucial to modernize and strengthen the Toxic Substances Control Act (TSCA) to provide the EPA with the tools necessary to achieve these goals and ensure global leadership in chemicals management.

We continue to be encouraged by the interest in TSCA reform indicated by the introduction of several bills in recent years, the hearings on TSCA related issues that are being held, and the discussions that are taking place. Key stakeholders share common principles on how best to improve our chemicals management programs. We at the EPA remain committed to working with this committee and others in both the House and Senate, members of the public, the

environmental community, the chemical industry, the states, and other stakeholders to improve and update TSCA.

As you know, chemicals are found in almost everything we buy and use. They contribute to our health, our well-being, and our prosperity. However, we believe that it is essential that chemicals are safe. While we have a better understanding of the environmental impacts, exposure pathways, and health effects that some chemicals can have than we did when TSCA was passed in 1976, under the existing law it is challenging to act on that knowledge.

TSCA gives the EPA jurisdiction over chemicals produced, used, and imported into the United States. Unlike the laws applicable to pesticides and drugs, TSCA does not have a mandatory program that requires the EPA to conduct a review to determine the safety of existing chemicals. In addition, TSCA places burdensome legal and procedural requirements on the EPA before the agency can request the generation and submission of health and environmental effects data on existing chemicals.

While TSCA was an important step forward when it was passed almost forty years ago, it has proven to be a challenging tool for providing the protection against chemical risks that the public rightfully expects. It is the only major environmental statute that has not been updated or revised since enactment. We believe the time is now to significantly strengthen the effectiveness of this outdated law.

When TSCA was enacted, it grandfathered in, without any evaluation, about 60,000 chemicals that were in commerce at the time. The statute did not provide adequate authority for the EPA to reevaluate these existing chemicals as new concerns arose or science was updated. The law also failed to grant the EPA effective tools to compel companies to generate and provide toxicity data.

It has also proven challenging in some cases to take action to limit or ban chemicals that the EPA has determined pose a significant health concern. For example, in 1989, after years of study and with strong scientific support, the EPA issued a rule phasing out most uses of asbestos in products. Yet, in 1991, a federal court overturned most of this action because it found the rule had failed to comply with the requirements of TSCA.

As a result, in the more than three and a half decades since the passage of TSCA, the EPA has only been able to require testing on a little more than 200 of the original 60,000 chemicals listed on the TSCA Inventory, and has regulated or banned only five of these chemicals under TSCA's section 6 authority, the last of which was in 1990. In the 25 years since, the EPA has largely relied on voluntary action to collect data and address risks. In the absence of additional federal action, an increasing number of states are taking actions on chemicals to protect their residents and the private sector is making their own decisions about chemicals to protect their interests and respond to consumers.

This Administration is committed to using the current statute to the fullest extent possible but the nature of the statute has limited progress. In the last six years, the EPA has identified more than

80 priority chemicals for assessment under TSCA. We have completed final risk assessments on specific uses of five chemicals. Of these, two show no significant risk. The remaining three show risk. To address the risks identified in these three assessments, the EPA is considering pursuing action under Section 6 of TSCA.

It is clear that even with the best efforts under current law and resources, we need to update and strengthen TSCA and provide the EPA with the appropriate tools to protect the American people from exposure to harmful chemicals. The EPA believes that it is critical that any update to TSCA include certain components.

In September 2009, the Administration announced the attached set of six principles to update and strengthen TSCA. The principles are:

Principle 1: Chemicals Should Be Reviewed Against Safety Standards That Are Based on Sound Science and Reflect Risk-based Criteria Protective of Human Health and the Environment.

Principle 2: Manufacturers Should Provide EPA With the Necessary Information to Conclude That New and Existing Chemicals Are Safe and Do Not Endanger Public Health or the Environment.

Principle 3: Risk Management Decisions Should Take into Account Sensitive Subpopulations, Cost, Availability of Substitutes and Other Relevant Considerations.

Principle 4: Manufacturers and EPA Should Assess and Act on Priority Chemicals, Both Existing and New, in a Timely Manner.

Principle 5: Green Chemistry Should Be Encouraged and Provisions Assuring Transparency and Public Access to Information Should Be Strengthened.

Principle 6: EPA Should Be Given a Sustained Source of Funding for Implementation.

While the Administration does not have a position on the discussion draft, there are several important observations that I would like to offer. As stated in the principles above, we feel strongly that updated legislation should include improvements that will provide the EPA with the ability to make timely decisions if a chemical poses a risk and the ability to take action, as appropriate, to address that risk.

The Administration principles state that priority chemicals should be assessed and acted upon in a timely manner, with clear, enforceable and practicable deadlines for completion of chemical reviews. The discussion draft does provide the EPA with more effective authority to compel the generation of data on existing chemicals. The discussion draft should give the EPA authority to set priorities for conducting safety reviews on existing chemicals based on relevant risk and exposure considerations. We believe this authority is vitally important to assuring the American public that the chemicals that they find in the products they buy and use are safe.

The discussion draft includes two means by which risk evaluations could be initiated for existing chemicals under section 6. The first is that EPA would be required to conduct a risk evaluation

upon a finding that the combination of hazard from and exposure to a particular chemical substance has the potential to create an unreasonable risk of injury to health or the environment. The second allows for a chemical manufacturer to request that EPA conduct a risk evaluation for a particular chemical substance. In practice, this would likely lead to EPA focusing the majority of its limited risk evaluation resources on completing evaluations for chemical substances requested by industry, which, once requested, start the clock ticking on a number of deadlines. This could result in evaluations for the chemicals with the most potential for risk being put off indefinitely, while EPA works on the evaluations requested by industry.

Additionally, the requirement that EPA make an affirmative finding of the potential for unreasonable risk, prior to initiating a risk evaluation, creates a possible analytical "catch-22" in which EPA must make a finding regarding the potential for risk prior to beginning the risk evaluation process. I note that once the EPA is able to conduct an evaluation that finds risk, the discussion draft appears to impose rigorous deadlines for taking regulatory action to reduce those risks. However, in many cases the deadlines in the draft are unreasonably short, which we would be happy to discuss with committee staff at the appropriate time.

As stated earlier, the use of section 6 of TSCA to limit or ban a chemical that poses a significant risk has been a major challenge. The discussion draft clearly removes TSCA's requirement that the EPA demonstrate it is using the least burdensome requirements needed to provide adequate protection. Administration Principle 1 states that chemicals should be reviewed against a safety standard based on sound science and risk-based criteria protective of human health and the environment. By this, we mean that assessment of safety should not include consideration of

costs or the availability of substitutes. The draft appears consistent with Principle 1 in that it specifies that risk assessments should include consideration of information on potentially exposed subpopulations but not information on cost and other factors not directly related to health or the environment. The discussion draft is ambiguous on how EPA is to incorporate cost and other factors into a risk management rule under section 6(a).

A chemical safety program is not credible if it is clear that resources are inadequate to do the work that is necessary to determine safety. In the current discussion draft, while the cap on fees is eliminated, there are not provisions that ensure EPA will be given a sustained source of funding for implementation, as articulated in Principle 6.

The discussion draft is consistent with the Administration principles in the area of transparency and availability of information on chemicals, including giving the EPA the ability to share chemical data with state, local and tribal governments.

Mr. Chairman, thank you again for your leadership on TSCA reform. I will be happy to answer any questions you or other members may have.

APPENDIX: Essential Principles for Reform of Chemicals Management Legislation

The U.S. Environmental Protection Agency (EPA) is committed to working with the Congress, members of the public, the environmental community, and the chemical industry to reauthorize the Toxic Substances Control Act (TSCA). The Administration believes it is important to work together to quickly modernize and strengthen the tools available in TSCA to increase confidence that chemicals used in commerce, which are vital to our Nation's economy, are safe and do not endanger the public health and welfare of consumers, workers, and especially sensitive sub-populations such as children, or the environment.

The following Essential Principles for Reform of Chemicals Management Legislation (Principles) are provided to help inform efforts underway in this Congress to reauthorize and significantly strengthen the effectiveness of TSCA. These Principles present Administration goals for updated legislation that will give EPA the mechanisms and authorities to expeditiously target chemicals of concern and promptly assess and regulate new and existing chemicals.

Principle No. 1: Chemicals Should Be Reviewed Against Safety Standards That Are Based on Sound Science and Reflect Risk-based Criteria Protective of Human Health and the Environment.

EPA should have clear authority to establish safety standards that are based on scientific risk assessments. Sound science should be the basis for the assessment of chemical risks, while recognizing the need to assess and manage risk in the face of uncertainty.

Principle No. 2: Manufacturers Should Provide EPA With the Necessary Information to Conclude That New and Existing Chemicals Are Safe and Do Not Endanger Public Health or the Environment.

Manufacturers should be required to provide sufficient hazard, exposure, and use data for a chemical to support a determination by the Agency that the chemical meets the safety standard. Exposure and hazard assessments from manufacturers should be required to include a thorough review of the chemical's risks to sensitive subpopulations.

Where manufacturers do not submit sufficient information, EPA should have the necessary authority and tools, such as data call in, to quickly and efficiently require testing or obtain other information from manufacturers that is relevant to determining the safety of chemicals. EPA should also be provided the necessary authority to efficiently follow up on chemicals which have been previously assessed (e.g., requiring additional data or testing, or taking action to reduce risk) if there is a change which may affect safety, such as increased production volume, new uses or new information on potential hazards or exposures. EPA's authority to require submission of use and exposure information should extend to downstream processors and users of chemicals.

Principle No. 3: Risk Management Decisions Should Take into Account Sensitive Subpopulations, Cost, Availability of Substitutes and Other Relevant Considerations

EPA should have clear authority to take risk management actions when chemicals do not meet the safety standard, with flexibility to take into account a range of considerations, including children's health, economic costs, social benefits, and equity concerns.

Principle No. 4: Manufacturers and EPA Should Assess and Act on Priority Chemicals, Both Existing and New, in a Timely Manner

EPA should have authority to set priorities for conducting safety reviews on existing chemicals based on relevant risk and exposure considerations. Clear, enforceable and practicable deadlines applicable to the Agency and industry should be set for completion of chemical reviews, in particular those that might impact sensitive sub-populations

Principle No. 5: Green Chemistry Should Be Encouraged and Provisions Assuring Transparency and Public Access to Information Should Be Strengthened

The design of safer and more sustainable chemicals, processes, and products should be encouraged and supported through research, education, recognition, and other means. The goal of these efforts should be to increase the design, manufacture, and use of lower risk, more energy efficient and sustainable chemical products and processes.

TSCA reform should include stricter requirements for a manufacturer's claim of Confidential Business Information (CBI). Manufacturers should be required to substantiate their claims of confidentiality. Data relevant to health and safety should not be claimed or otherwise treated as CBI. EPA should be able to negotiate with other governments (local, state, and foreign) on appropriate sharing of CBI with the necessary protections, when necessary to protect public health and safety.

Principle No. 6: EPA Should Be Given a Sustained Source of Funding for Implementation

Implementation of the law should be adequately and consistently funded, in order to meet the goal of assuring the safety of chemicals, and to maintain public confidence that EPA is meeting

that goal. To that end, manufacturers of chemicals should support the costs of Agency implementation, including the review of information provided by manufacturers.

Appointment

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 11/3/2015 5:59:32 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]

Subject: Sen. Markey TSCA TA on Nomenclature (attached)
Attachments: Markey.TSCA TA.Nomenclature.docx
Location: Call in { Personal Phone / Ex. 6 code Personal Phone / Ex. 6

Start: 11/6/2015 4:00:00 PM
End: 11/6/2015 5:00:00 PM
Show Time As: Tentative

Michal – if time available at the end, we also could discuss articles. Thanks,
Sven

Markey.TSCA TA.Nomenclatur...

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/13/2015 3:29:55 PM
To: 'Wilkerson, Jessica' [Jessica.Wilkerson@mail.house.gov]; 'Couri, Jerry' [JerryCouri@mail.house.gov]
Subject: RE: Invitation to Testify 4/14/15
Attachments: EPA test.TSCA.4.14.15.docx

Jessica,
Attached please find Jim Jones's testimony for the hearing on Tuesday, April 14, 2015, at 10:15 p.m. before the Subcommittee on Environment and the Economy entitled, "H.R. ____, the TSCA Modernization Act of 2015." We will bring the completed truth in testimony form to the hearing. Please let me know if any questions.
Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Wilkerson, Jessica [mailto:Jessica.Wilkerson@mail.house.gov]
Sent: Thursday, April 09, 2015 3:51 PM
To: Kaiser, Sven-Erik
Subject: Invitation to Testify 4/14/15

Assistant Administrator Jones,

Attached is a courtesy copy of your invitation to testify on Tuesday, April 14, 2015, at 10:15 p.m., at the Subcommittee on Environment and the Economy hearing entitled, "H.R. ____, the TSCA Modernization Act of 2015." The formal invitation has been sent in the mail.

Please submit your testimony, truth in testimony, and CV forms electronically to me (jessica.wilkerson@mail.house.gov) by close of business Friday, April 10, 2015.

I have also attached instructions for submitting testimony, a truth in testimony form with instructions, and the 114th Congress Committee rules. Please let me know if you have any questions or concerns.

Thank you,

Jessica Wilkerson | Legislative Clerk
U.S. House Committee on Energy and Commerce
(202) 225-2927

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/10/2015 3:44:57 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]; Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
Subject: RE: SEPW TSCA TA Request

Ok – will let folks know. At a minimum we will have our attorneys, Brian Grant and David Berol on the line.
Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Friday, April 10, 2015 11:41 AM
To: Kaiser, Sven-Erik; Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TSCA TA Request

Thanks. Sven, we'd like to invite Richard Denison and Mike Walls to participate in the call if that would be ok with you. We've had a robust stakeholder conversation on these two issues and it would help streamline discussions if you are ok to include them. Please let me know.

Thanks.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 10, 2015 11:02 AM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TSCA TA Request

For the call at 2pm today, please cal Personal Phone / Ex. 6 code Personal Phone / Ex. 6 Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Friday, April 10, 2015 10:57 AM
To: Karakitsos, Dimitri (EPW); Kaiser, Sven-Erik
Subject: RE: SEPW TSCA TA Request

Same. Do you have a good call-in number we can use?

From: Karakitsos, Dimitri (EPW)
Sent: Friday, April 10, 2015 10:56 AM
To: 'Kaiser.Sven-Erik@epa.gov'; Black, Jonathan (Tom Udall)
Subject: Re: SEPW TSCA TA Request

Works for me.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 10, 2015 10:51 AM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TSCA TA Request

Jonathan and Dimitri,
Any availability around 2-3 pm today for a call? Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Friday, April 10, 2015 9:58 AM
To: Kaiser, Sven-Erik; Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TSCA TA Request

We're under a quick turn-around time-constraint. Perhaps we can get on the phone to discuss some of these things to facilitate a faster discussion?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 10, 2015 9:31 AM
To: Karakitsos, Dimitri (EPW)
Cc: Black, Jonathan (Tom Udall)
Subject: SEPW TSCA TA Request

Dimitri,
Thank you for the technical assistance request. We'll get to work on it. Please let me know your sense of priority on this request as we are preparing for a House TSCA hearing on Tuesday, April 14. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Thursday, April 09, 2015 5:13 PM
To: Kaiser, Sven-Erik

Cc: Black, Jonathan (Tom Udall)
Subject: EPA TA

Sven,

Here are a few things we would greatly appreciate some EPA TA on. We may need to discuss some further so if a phone call would be helpful please just let me know and thanks in advance for the help. I am also happy to work with you to help facilitate a call between your folks and some interested parties on the articles language if you think that would help.

Dimitri

Articles
It was my understanding that under current TSCA if EPA were looking to regulate an article or articles the Agency would already have somewhat of a higher bar and do some level of extra analysis of finding there is an exposure to a chemical substance from an article or group of articles. I had a brief conversation that I interpreted as the Agency not being against some heightened review to determine when article specific regulations were necessary but clearly we understand the challenges and hurdles the language we have in the bill today seem to cause. Below are two proposals, one from an outside counsel which I don't think addresses all your concerns and one that we worked up to see what you all thought. It is important to us to have something on articles in the bill, striking is not much of an option so if you all can please review and provide guidance we would appreciate.

- Proposed language – If the Administrator intends to prohibit or otherwise restrict an article, or a category of articles that perform similar functions and have similar patterns of exposure, on the basis of a chemical substance contained in that article or category, the Administrator shall have evidence of significant exposure to the chemical substance from such article or category.
- Draft staff language - New 3A(h)(2)(C)(ii)(III): " when considering the regulation of an article, or a category of articles, in a rulemaking under section 6, clearly describe the exposure or exposures to the chemical substance determined by the Administrator to be associated with such articles or categories of articles."

Preemption
Waiver – in our State Waivers we have two separate provisions that require a showing of a "compelling state or local" condition or interest. Those provisions were not intended to mean that the state would have to show some different exposures or unique conditions to meet that requirement, it was simply that they had a genuine concern with the substance that led them to request the waiver. Is there some way to clarify?

Exceptions/No Preemption of State Statutes and Administrative Actions – these two provisions other than their intro paragraphs are identical. The request for clarification and TA comes from subsection A in both 1 and 2. I have concern that "for the purpose of satisfying or obtaining authorization or approval under any other federal law" is incredibly broad and could leave loop holes for states to regulate TSCA regulated chemical substances in ways inconsistent with EPA decisions under the law. If EPA for example (possibly not the most eloquent or well thought out example) found a product safe for use in an aerosol application yet a state banned it under their state law to comply with the CAA to reduce VOCs or some other air pollutant – maybe it is one option the state could take "for the purpose of satisfying or obtaining authorization or approval" but it may be one of a range of options – why should that be inconsistent with an EPA TSCA decision. I think at a minimum I would prefer language stating the state level restriction is "necessary" to satisfy or obtain authorization or approval rather than "for the purpose of."

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/2/2015 8:12:56 PM
BCC: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; 'Atcheson, Laura (EPW)' [Laura_Atcheson@epw.senate.gov]; 'Fox, Thomas (EPW)' [Thomas_Fox@epw.senate.gov]; Albritton, Jason (EPW) [Jason_Albritton@epw.senate.gov]; 'Glueck, James (Agriculture)' [James_Glueck@ag.senate.gov]; 'Behnam, Rostin (Agriculture)' [Rostin_Behnam@ag.senate.gov]; 'Cohen, Jacqueline' [jackie.cohen@mail.house.gov]; 'Couri, Jerry' [JerryCouri@mail.house.gov]; 'Goldberg, John' [John.Goldberg@mail.house.gov]; 'Jones, Keith' [Keith.Jones@mail.house.gov]; 'anne.simmons@mail.house.gov' [anne.simmons@mail.house.gov]; Distefano, Nichole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31d32a3a3a9e4591b5fdfc3eb96e8b78-Distefano,]; Borum, Denis [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f385dc95b8714c7cb74334eed0e1474d-DBorum]; Davis, CatherineM [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9977d3119e394dcf9cf819e79b52992b-Davis, Catherine]; Fowler, Jamie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b74e8771b8049e5bde0f26dc5b1de97-JFowler6]
Subject: Notification: Biotechnology Memo
Attachments: Embargoed Memo - Modernizing the Reg System for Biotech Products .pdf

Heads up on a memo and blog post on biotech that went out from OSTP today. https://www.whitehouse.gov/administration/eop/ostp/blog.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

EMBARGOED UNTIL 2:00 PM EST ON JULY 2, 2015

July 2, 2015

MEMORANDUM FOR HEADS OF FOOD AND DRUG ADMINISTRATION, ENVIRONMENTAL PROTECTION AGENCY, AND DEPARTMENT OF AGRICULTURE

FROM: John P. Holdren
Assistant to the President for Science and Technology
Director, Office of Science and Technology Policy

Howard Shelanski
Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget

Darci Vetter
Chief Agricultural Negotiator
United States Trade Representative

Christy Goldfuss
Managing Director, Council on Environmental Quality

SUBJECT: Modernizing the Regulatory System for Biotechnology Products[1]

Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.[2] This memorandum initiates a process to modernize the Federal regulatory system for the products of biotechnology and to establish mechanisms for periodic updates of that system. The objectives are to ensure public confidence in the regulatory system and to prevent unnecessary barriers to future innovation and competitiveness by improving the transparency, coordination, predictability, and

[1] For the purpose of this memo, "biotechnology products" refers to products developed through genetic engineering or the targeted or in vitro manipulation of genetic information of organisms, including plants, animals, and microbes. It also covers some of the products produced by such plants, animals, and microbes or their derived products as determined by existing statutes and regulations. Products such as human drugs and medical devices are not the focus of the activities described in this memo.
[2] "Improving Regulation and Regulatory Review", Executive Order 13563, January 18, 2011.

efficiency of the regulation of biotechnology products while continuing to protect health and the environment.

This memorandum shall be implemented consistent with applicable law, Executive Order 13563, Executive Order 13610, and the 2011 "Principles for Regulation and Oversight of Emerging Technologies" memorandum.[2, 3, 4] Through those policies, this Administration has sought regulatory approaches that protect health and the environment while reducing regulatory burdens and avoiding unjustifiably inhibiting innovation, stigmatizing new technologies, or creating trade barriers. These principles must now be applied to updating the regulatory framework and systems that regulate the products of biotechnology.

Background

In 1986, the Office of Science and Technology Policy (OSTP) issued the Coordinated Framework for the Regulation of Biotechnology (CF),[5] which describes the comprehensive Federal regulatory policy for ensuring the safety of biotechnology products. The CF sought to achieve a balance between regulation adequate to ensure the protection of health and the environment while maintaining sufficient regulatory flexibility to avoid impeding innovation. In 1992, OSTP issued an update to the CF[6] that sets forth a risk-based, scientifically sound basis for the oversight of activities that introduce biotechnology products into the environment. The update affirmed that Federal oversight should focus on the characteristics of the product and the environment into which it is being introduced, rather than the process by which the product is created.

Each of the Federal regulatory agencies with jurisdiction over the products of biotechnology has developed regulations and guidance documents to implement its authority under existing laws, resulting in a complex system for assessing and managing health and environmental risks of the products of biotechnology. While the current regulatory system for the products of biotechnology effectively protects health and the environment, in some cases unnecessary costs and burdens associated with uncertainty about agency jurisdiction, lack of predictability of timeframes for review, and other processes have arisen. These costs and burdens have limited the ability of small and mid-sized companies to navigate the regulatory process and of the public to understand easily how the safety of these products is assured; and, accordingly, they have the potential to reduce economic growth, innovation, and competitiveness.

Advances in science and technology, moreover, have dramatically altered the biotechnology landscape since the 1992 update of the CF. Such advances can enable the development of products that were not previously possible. A further update of the CF is needed to facilitate the appropriate Federal oversight by the regulatory system and increase transparency, while continuing to provide a framework for advancing innovation.

---

[3] "Identifying and Reducing Regulatory Barriers", Executive Order 13610, January 10, 2012.
[4] "Principles for Regulation and Oversight of Emerging Technologies", Memorandum for the Heads of Departments and Agencies, March 11, 2011.
[5] http://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf
[6] https://www.whitehouse.gov/sites/default/files/microsites/ostp/57_fed_reg_6753__1992.pdf

Goals and Guidance

Federal agencies that regulate biotechnology products should continually strive to improve predictability, increase efficiency, and reduce uncertainty in their regulatory processes and requirements. It is critical that these improvements:

- maintain high standards that are based on the best available science and that deliver appropriate health and environmental protection;
- establish transparent, coordinated, predictable, and efficient regulatory practices across agencies with overlapping jurisdiction; and
- promote public confidence in the oversight of the products of biotechnology through clear and transparent public engagement.

This memo initiates a process to help advance these aims, beginning with the following one-year objectives: (1) development of an updated CF to clarify the roles and responsibilities of the agencies that regulate the products of biotechnology; (2) formulation of a long-term strategy to ensure that the Federal regulatory system is equipped to efficiently assess the risks, if any, associated with future products of biotechnology while supporting innovation, protecting health and the environment, promoting public confidence in the regulatory process, increasing transparency and predictability, and reducing unnecessary costs and burdens; and (3) commissioning an external, independent analysis of the future landscape of biotechnology products.

The following elements will support the process to achieve these objectives:

Section I. Biotechnology Working Group Under the Emerging Technologies Interagency Policy Coordination Committee. The new Biotechnology Working Group under the Emerging Technologies Interagency Policy Coordination Committee (ETIPC) will include representatives from the Executive Office of the President, as well as the Environmental Protection Agency (EPA), Food and Drug Administration (FDA), and United States Department of Agriculture (USDA). The working group shall coordinate with other Federal agencies and offices as necessary.

Section II. Mission and Function of the Working Group. Within one year of the date of this memorandum, the working group shall take steps detailed below and others, as appropriate, to increase the transparency, coordination, predictability, and efficiency of the regulatory system for the products of biotechnology. Specifically, the working group shall:

(a) update the CF to clarify the current roles and responsibilities of the agencies that regulate the products of biotechnology, after input from the public, by clarifying:
    (i) which biotechnology product areas are within the authority and responsibility of each agency;
    (ii) the roles that each agency plays for different product areas, particularly for those product areas that fall within the responsibility of multiple agencies,

and how those roles relate to each other in the course of a regulatory assessment;

(iii) a standard mechanism for communication and, as appropriate, coordination among agencies, while they perform their respective regulatory functions, and for identifying agency designees responsible for this coordination function; and

(iv) the mechanism and timeline for regularly reviewing, and updating as appropriate, the CF to minimize delays, support innovation, protect health and the environment and promote the public trust in the regulatory systems for biotechnology products; and

(b) develop a long-term strategy to ensure that the Federal regulatory system is equipped to assess efficiently the risks, if any, associated with future products of biotechnology while supporting innovation, protecting health and the environment, maintaining public confidence in the regulatory process, increasing transparency and predictability, and reducing unnecessary costs and burdens by:

(i) developing a plan for periodic formal horizon-scanning assessments of new biotechnology products to ensure that regulatory agencies are prepared for future products well before they reach the regulatory system;

(ii) working with other Federal agencies, as appropriate, to develop a coordinated and goal-oriented plan for supporting the science that informs regulatory activities with regard to the assessment of biotechnology products, and to reflect these priorities in agency budget submissions starting with the fiscal year (FY) 2017 budget;

(iii) ensuring that product evaluations are risk-based and grounded in the best science available, including regularly adjusting regulatory activities based on experience with specific products and the environments into which those products have been introduced;

(iv) establishing a timetable and mechanisms to work with stakeholders to identify impediments to innovation, focusing on building new, and augmenting existing, stakeholder collaborations to inform efforts, increase transparency, streamline processes, reduce costs and response times, and ensure the protection of health and the environment;

(v) coordinating the development of tools and mechanisms for assisting small businesses developing biotechnology products to navigate the regulatory system;

(vi) identifying changes to authorities, regulations, and policies, if any, that could improve agencies' abilities to assess expeditiously the potential impacts and risks arising from future products of biotechnology and to ensure the transparency, predictability, and efficiency of regulatory oversight for such products;

(vii) initiating development of a modernized, user-friendly set of tools for presenting the regulatory agencies' authorities, practices, and bases for decision making for the regulation of biotechnology products to the

public, including digital services to improve the interactions between the FDA, EPA, USDA, the general public, and product developers and updating these tools and practices regularly to ensure optimal transparency; and

(viii) proactively engaging with the public to discuss how the Federal government uses a risk-based, scientifically sound approach to regulating the products of biotechnology, and clearly communicating to the public which types of products are regulated, which types of products are not regulated, and why.

Sec. III. Independent Assessment. The EPA, FDA, and USDA shall commission an external, independent analysis of the future landscape of biotechnology products that will identify (1) potential new risks and frameworks for risk assessment and (2) areas in which the risks or lack of risks relating to the products of biotechnology are well understood. The review will help inform future policy making. Due to the rapid pace of change in this arena, an external analysis should be completed at least every five years.

Sec. IV. Budgeting for Efficiency. The EPA, FDA, and USDA shall work with OSTP and OMB, within the annual President's budget formulation process, to develop a plan for supporting the implementation of this memo in Agency FY 2017 budget requests and, as appropriate, in future budget submissions.

Sec. V. Annual Reporting. For at least five years, starting one year after the release of the strategy described in Section II, the working group will produce an annual report on specific steps that agencies are taking to implement that strategy and any other steps that the agencies are taking to improve the transparency, coordination, predictability, and efficiency of the regulation of biotechnology products. This report will be made available to the public by the Executive Office of the President.

Sec. VI. General Provisions. Nothing in this memorandum shall be construed to impair or otherwise affect:

(a) the mission as established by law for any agency;
(b) the authority granted by law to any agency or the head thereof; or
(c) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, regulatory, or legislative proposals.

Nothing in this memorandum shall be construed to require the disclosure of confidential business information or trade secrets, classified information, law enforcement sensitive information, or other information that must be protected in the interest of national security or public safety.

This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/2/2015 6:51:39 PM
To: Couri, Jerry [JerryCouri@mail.house.gov]
CC: McCarthy, David [David.McCarthy@mail.house.gov]
Subject: Re: July 10 Event

Thanks

On Jul 2, 2015, at 2:47 PM, "Couri, Jerry" <JerryCouri@mail.house.gov> wrote:

We don't need Jim, as long as we have someone senior who can speak to these matters.

Committee Report is based only on the Committee reported bill. It cannot opine on any matters added after committee consideration.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, July 02, 2015 2:36 PM
To: Couri, Jerry
Subject: Re: July 10 Event

Jerry,
We're still discussing the event. Heads up that Jim Jones is out that week. Also, just checking, the committee report is based on the committee's bill and not the final bill that passed the house, right? We're still having version issues at our end. Thanks,
Sven

On Jul 1, 2015, at 12:42 PM, "Couri, Jerry" <JerryCouri@mail.house.gov> wrote:

Sven:

Would like to talk to you today about nailing down either Jim or some other senior TSCA person to come in and participate in a discussion with members and regulated stakeholders about changes to regulations in section 8.

Thanks,

- <!--[if !supportLists]--><!--[endif]-->Jerry

Gerald S. Couri
Senior Environmental Policy Advisor | Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Building | 202.226.9603 (direct)
<image001.png><image002.png><image003.png><image004.png><image005.png>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/2/2015 6:36:23 PM
To: Couri, Jerry [JerryCouri@mail.house.gov]
Subject: Re: July 10 Event

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- <!--[if !supportLists]--><!--[endif]-->Jerry

Gerald S. Couri
Senior Environmental Policy Advisor | Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Building | 202.226.9603 (direct)
<image001.png><image002.png><image003.png><image004.png><image005.png>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/16/2015 4:30:47 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
CC: Joseph, Avenel (Markey) [Avenel_Joseph@markey.senate.gov]
Subject: Sen. Markey TSCA TA request on FR document
Attachments: 49FR39011.pdf

Michal – I think the attached document is what you are looking for. We will have a response shortly on the SNUR TA request. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, June 16, 2015 11:55 AM
To: Kaiser, Sven-Erik
Cc: Joseph, Avenel (Markey)
Subject: RE: Sen. Markey TSCA TA request on SNURs

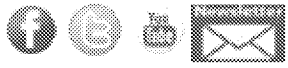
Also, could you pls send this FR document? I tried to find it online but was unsuccessful, maybe because it is so old.

Thanks
Michal

49 Fed. Reg. 35011, 35014 (Sept. 5, 1984)

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, June 15, 2015 4:54 PM
To: Freedhoff, Michal (Markey)
Cc: Joseph, Avenel (Markey)
Subject: Sen. Markey TSCA TA request on SNURs

Michal – got it – will circulate. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, June 15, 2015 4:49 PM
To: Kaiser, Sven-Erik
Cc: Freedhoff, Michal (Markey); Joseph, Avenel (Markey)
Subject: TSCA TA - SNURs

Sven

In discussing the new ly added SNUR provision with various parties, we were provided with the pasted statistics below. Could you tell us, for each year listed below, how many SNURs EPA issued (and how many of those were applied to articles)? How many of the SNUNs listed below applied to articles? Finally, does EPA concur with the statement that SNURS act as a defacto barrier to engaging in a significant new use (and why or why not?)?

Also, as a general matter, when we talked to Jim he told us that what is in S 697 on this matter is EPA's general current practice, ie that if it intends to do a notification about an article it does assess exposure first. What many have raised concerns with about the S 697 language (also pasted below) is not necessarily a concern about EPA's practice, but of the potential for the EPA's practice to become litigatable. For example, wouldn't the words "affirmative" and "reasonable" be words that could be litigated if an articles manufacturer had an issue with what EPA was doing?

Thanks
Michal

"In theory, SNURs are simply requirements to submit information to EPA before engaging in a significant new use. In practice, SNURS act as a *de facto* barrier to engaging in a significant new use. This may be seen by the paucity of significant new use notices (SNUNs) submitted each year. EPA currently has about 1,685 SNURs, some of which apply to multiple chemicals. Yet almost no SNUNs are filed for those SNURs. See the following:

- FY 2005: 4 SNUNs were filed
- FY 2006: 8 SNUNs were filed
- FY 2007: 6 SNUNs were filed
- FY 2008: 8 SNUNs were filed
- FY 2009: 7 SNUNs were filed
- FY 2010: 2 SNUNs were filed
- FY 2011: 11 SNUNs were filed"

"(3) ARTICLE CONSIDERATION.—The Administrator may require the notification for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(B) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule warrants notification.";

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/15/2015 2:47:40 PM
To: 'Wagner, Jen (Markey)' [Jen_Wagner@markey.senate.gov]
Subject: RE: Sen. Markey TA Request on Asbestos Bill

Jen – please let me know some times you are available for a call today. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Wagner, Jen (Markey) [mailto:Jen_Wagner@markey.senate.gov]
Sent: Monday, June 15, 2015 10:26 AM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Markey TA Request on Asbestos Bill

Sven,
There are only two new proposed sections (217 and 218). The intent is to have an enforcement mechanism to ensure that the rules are actually issued as required by this bill. The enforcement for violations (e.g., a seller's failure to disclose) is achieved by other text in the bill. That's why there were separate sections (e) "enforcement of issuance of regulations" and (f) "enforcement".

The way I read your clarification leads me to believe that our section (e) is unnecessarily duplicative (and poorly worded by leg counsel). Your clarification also leads me to believe that some additional text (similar to 217(f)(1)-(3) "enforcement") is needed for our section 218.

Regarding private lawsuits, the answer is yes to sec 217 (which is why the language is already there as Sec 217(f)(4)).

Would it be easier to speak by phone? I have availability today.

~Jen

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, June 15, 2015 10:12 AM
To: Wagner, Jen (Markey)
Subject: RE: Sen. Markey TA Request on Asbestos Bill

Jen,
I'm not sure if we're getting to your question about the enforcement language in new section 217(e). If the intent is to authorize citizen civil suits against the Administrator -- it may create unnecessary confusion (the reference to issuance of regulations is a problem)

If the intent is to authorize citizen civil suits against parties who fail to comply with the regulations once the regulations have been issued by the Administrator and are in effect -- then it might be best to come up with a new title and clarify a few other things regarding that type of citizen suit.

If the plan is to have each of the proposed new sections (217, 218, etc) authorize citizen civil suits against private parties for violations, then we might suggest one enforcement section that references all of the new sections OR consider whether the enforcement provisions in 15 USC 2614, 2615, and 2616 could be used (with a few changes as necessary).

If helpful, perhaps we could set up a call to discuss. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Wagner, Jen (Markey) [mailto:Jen_Wagner@markey.senate.gov]
Sent: Monday, June 15, 2015 10:04 AM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Markey TA Request on Asbestos Bill

Sven, thanks so much for this. I was just in the middle of drafting a reply to the enforcement question.

Our intent was to ensure that 15 USCA 2619(a) would be applicable. Given your clarification from last week that this is the case even without such language, does our section 217(e) create confusion?

Would it be technically better to remove our 217(e) altogether or reword it to specifically reference 15 USC 2619(a) and then include that identical language to our 218(e) as well?

Thanks for your help walking through this last technical detail.

Best,
Jen

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, June 15, 2015 10:01 AM
To: Wagner, Jen (Markey)
Subject: Sen. Markey TA Request on Asbestos Bill

Jen,
Following up on your information request, please see the attached items. The first two, FY14 and FY15 National Program Manager Guidances, lay out EPA's compliance and enforcement program. A key area for your attention is the FY 2014 NPMG, beginning on Page 30, where the TSCA National Program activities and priorities are identified. The FY15 NPMG updates identifies any major changes to the various programs as described in the FY14 NPMG. The TSCA program does not have any major changes in FY15, so the FY15 NPMG does not have anything to say regarding TSCA.

As to state funding, attached is the funding chart EPA sends to the Regional Offices identifying how much each state and program was allocated under the FY15 TSCA State and Tribal Assistance Grants (STAG). The attachment shows the total $4,919,000. The TSCA STAG funding has two sources. Section 28 of TSCA funds the AHERA and PCB programs, and section 404(g) of TSCA funds the lead-paint program. Section 28 requires the state to match 25% of the grant.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Begin forwarded message:

From: "Wagner, Jen (Markey)" <Jen_Wagner@markey.senate.gov>
Date: June 12, 2015 at 12:37:28 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: FW: Sen. Markey TA Request on Asbestos Bill

One more question that came up…

Could you please tell me what the overall TSCA enforcement spending is currently and how much EPA distributes as grants to states for enforcement annually? This information is needed to determine a reasonable figure for the section of the bill on "funds for enforcement".

Again, we really would like to have the remaining questions answered today if possible.

Thanks,
Jen

From: Wagner, Jen (Markey)
Sent: Friday, June 12, 2015 12:20 PM
To: 'Kaiser, Sven-Erik'
Subject: FW: Sen. Markey TA Request on Asbestos Bill

Sven,
I'm looking for some additional clarification about whether additional text would be required in this bill if the intent was to allow for citizen petitions/suits to make sure that rules are promulgated to implement the bill's provisions.

If we could get more information on that today, that would be much appreciated.

Thanks,
Jen

From: Wagner, Jen (Markey)
Sent: Thursday, June 11, 2015 3:58 PM
To: 'Kaiser, Sven-Erik'
Subject: RE: Sen. Markey TA Request on Asbestos Bill

Sven,
Could you please point me to the TSCA enforcement priorities document that was referenced during the call this morning?

Also, I would like clarification on the TA comments regarding citizen suits to enforce the deadlines for promulgating rules. They appear as comments A21, A46, and A71. I didn't have time to ask about this specific point, but I was wondering if I could get technical feedback about whether additional language in the bill is necessary. We take your point for Section 2 (updating the AIA of 1988). But with regard to the other sections, we included an enforcement mechanism

in Section 3 (Shown as (e) "Enforcement of Issuance of Regulations") and the bill's Sections 3,4, and 5 – we believe – would still leave 15 USC 2647(d)-(f) intact and applicable. As a related matter, does 15 USC 2620 (of TSCA Title I) apply as well?

Thanks for any clarification you could give me on this.

Jen

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, June 10, 2015 3:21 PM
To: Wagner, Jen (Markey)
Subject: RE: Sen. Markey TA Request on Asbestos Bill

Jen – 9 am works – Personal Phone / Ex. 6 code Personal Phone / Ex. 6 I'll send an invite. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Wagner, Jen (Markey) [mailto:Jen_Wagner@markey.senate.gov]
Sent: Wednesday, June 10, 2015 2:57 PM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Markey TA Request on Asbestos Bill

Thanks Sven. I will try to block anything from going on my calendar in the hopes that a call will work with you all.

~Jen

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, June 10, 2015 1:44 PM
To: Wagner, Jen (Markey)
Subject: RE: Sen. Markey TA Request on Asbestos Bill

Jen – I'll check with folks and see what we can set up with the times you provided. Please let me know if any additional questions. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Wagner, Jen (Markey) [mailto:Jen_Wagner@markey.senate.gov]
Sent: Wednesday, June 10, 2015 12:43 PM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Markey TA Request on Asbestos Bill

Sven,

Could we please schedule a call with your best asbestos folks to walk through some of the technical assistance? I would like to get some clarification on a few areas, including how the waiver system is operating in practice and pros and cons of replacing the waiver system with primacy language.

It is important that this call happen this week. Here are some windows that would work for me:

Thursday: 9am-10am, 2-2:30pm, or 3:30pm-5:30pm
Friday: any time before 1pm

Thank you so much.
~Jen

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, June 09, 2015 1:48 PM
To: Wagner, Jen (Markey); Freedhoff, Michal (Markey); Joseph, Avenel (Markey)
Subject: Sen. Markey TA Request on Asbestos Bill

Jen,
This responds to your request for technical assistance on the draft asbestos bill. We have the following general comments along with the attached line by line comments.

General comments:

- Responsibility for implementing most of the new requirements would appear to fall largely on states, although EPA would have new oversight and data management responsibilities, along with a grant program. EPA would need to do a rule on the reporting requirements, a separate rule requiring disclosure on building permit applications, revise regulations on state waivers, and issue a notice on how to submit data.

- Encourage consistency in use of terms. For example, "asbestos containing material" is not used consistently throughout the Act, which it may make it unclear whether both asbestos and asbestos containing material are covered.

- The date range of "before 1981 (or no later than 1980)" is not a bright line for whether asbestos is present in buildings. Considering the "Corrosion Proof Fittings" case and the overturned EPA Asbestos Ban and Phaseout Rule under TSCA, asbestos containing materials may be present in buildings built after 1981. Today, asbestos products may still be manufactured, imported, distributed and sold in the U.S. Note: It appears that the inclusion of "built before 1981" may have been included based on the OSHA asbestos regulation's use of "buildings constructed no later than 1980."

    - **1926.1101**
      https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9995
    - **1910.1001**
      https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10862
    - However, this OSHA provision "buildings constructed no later than 1980" is for the presumption of asbestos in a building. Building owners must presume certain materials

in buildings built before 1980 contain asbestos. Building owners, however, are still responsible for any asbestos within their buildings built after 1980.

- The term "risk assessment" as used (e.g., Section 3(b)(3)) may imply a more costly, unnecessary and undefined activity when applied to a residential setting. The term "inspection" is used in the current context of the TSCA asbestos regulations and the asbestos professional industry when looking for the presence of asbestos.

- It is not clear what is meant by the term "asbestos hazard(s)" throughout the proposed amendment. For lead paint, the term "lead based paint hazard" is defined in the Residential Lead-Based Paint Hazard Reduction Act of 1992 which helps regulatorily in determining what is identified as a hazard and how it should be addressed. Leaving "asbestos hazard(s)"undefined may create situations where defining a hazard is open to interpretation.
- Suggest considering whether criminal enforcement provisions be added to the bill.

We would be open to further discussion on that and any portion of the entire TA if helpful. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy position of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Best,
Sven

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202-566-2753

From: Wagner, Jen (Markey) [mailto:Jen_Wagner@markey.senate.gov]
Sent: Wednesday, May 13, 2015 1:05 PM
To: Kaiser, Sven-Erik
Subject: feedback sought on draft legislation

Sven,
I hope you are doing well. We wanted to share with you a discussion draft of a bill my boss, Senator Markey, plans to introduce. We welcome your general feedback but were hoping you might have specific recommendations for Section 4 of the bill and, in particular, the selection of waiver language or primacy language. I've attached a copy of the text as well as a copy of our one-page summary.

If you are able to provide feedback by end of next week, that would be appreciated. Thanks in advance.

Kind regards,
Jen Wagner

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